Exhibit A

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO / OAKLAND DIVISION

RASHID HUNTER, individually and on behalf of all others similarly situated,

Plaintiff,

v.

MEDTRONIC, INC., MEDTRONIC INTERNATIONAL TECHNOLOGY, INC. formerly known as MEDTRONIC PUERTO RICO, INC., and MEDTRONIC PUERTO RICO OPERATIONS CO.,

Defendants.

Case No. 6474

CLASS ACTION COMPLAINT FOR DECLARATORY, INJUNCTIVE AND EQUITABLE RELIEF AND DAMAGES

DEMAND FOR JURY TRIAL

Plaintiff Rashid Hunter, by his undersigned counsel, individually and for all other residents and citizens of the State of California who are similarly situated, hereby commences this individual and Class Action against Medtronic, Inc., Medtronic International Technology, Inc. formerly known as Medtronic Puerto Rico, Inc. and Medtronic Puerto Rico Operations Co. (hereinafter collectively "Defendants" or "Medtronic," unless otherwise stated) for compensatory, equitable, injunctive, and declaratory relief. Plaintiff makes the following allegations based upon his personal knowledge as to his own acts, and upon information and belief, as well as upon his

attorneys' investigative efforts as to Medtronic's actions and misconduct, and alleges as follows:

PARTIES

1. Individual and representative Plaintiff Rashid Hunter is a citizen and resident of the County of Alameda in the State of California.

2. Defendant Medtronic, Inc., is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Medtronic develops technology to treat conditions such as heart disease and other illnesses. Medtronic manufactures medical devices and sells them worldwide. Medtronic's Cardiac Rhythm Disease Management Division ("CRM Division") is the division that develops, researches, advertises, promotes, markets and sells all of Medtronic implantable defibrillators ("ICDs"), and leads, some of which are marketed under the trade name "Sprint Fidelis." CRM Division's operations are principally conducted out of its facilities at Cardiac Rhythm Disease Management at 7000 Central Ave., Minneapolis, Minnesota 55432.

3. Defendant Medtronic International Technology, Inc., formerly known as Medtronic Puerto Rico, Inc., is a corporation existing by virtue of the laws of the Territory of Puerto Rico, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

4. Defendant Medtronic Puerto Rico Operations Co., is a corporation existing by virtue of the laws of the Territory of Puerto Rico, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

5. Medtronic International Technology, Inc., and Medtronic Puerto Rico Operations Co., are wholly owned subsidiaries of Medtronic, Inc., which formulate, develop, manufacture and sterilize the devices at issue in this lawsuit.

INTRODUCTION

6. Medtronic designs, researches, develops, manufactures, tests, markets, advertises, promotes, distributes, and sells products that treat cardiac arrhythmias, heart failure, and coronary and peripheral vascular disease. An arrhythmia is an irregular cardiac rhythm, which can cause significantly decreased cardiac output and ultimately, death. Medtronic holds itself out as "the global leader in medical technology, alleviating pain, restoring health and

extending life for millions of people around the world." *See* 2005 Annual Statement, Medtronic, Inc.

7. A number of devices designed to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms are available from Medtronic and other manufacturers, including implantable cardiac defibrillators ("ICDs"). ICDs contain pacemakers as well as defibrillators; while a pacemaker is used primarily to correct slow heart rates, an ICD detects and corrects both fast and slow heart rates. The pacemaker portion corrects the slow rates and the anti-tachycardia portion can "over-drive pace" rapid rates. The defibrillator portion can shock ventricular tachycardia and ventricular fibrillation to stop the heart and allow an appropriate rhythm to take over.

8. ICDs are designed to be implanted primarily under the skin of the chest wall. The device's power source, or pulse generator, is implanted in a pouch formed in the chest wall generally over the left pectoralis major muscle.

9. Typically, wires called leads are inserted through a major vein and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and can administer an electric shock to abort a dangerous "over-drive pace," a very rapid rhythm, or pace the heart at a normal rhythm if an irregularity is detected.

10. Such devices are used in patients, like Plaintiff Rashid Hunter and the Class members (hereinafter "Plaintiff" and "Class members"), who have arrhythmias or irregular heartbeats that are considered life-threatening. The Class members with these medical problems include patients who are at risk for ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), and ventricular tachycardia (excessively rapid heartbeat) that are poorly controlled by medication. These arrhythmias or irregular heart beats can result in the loss of consciousness or death, unless the patient receives therapy from an appropriate device to put the heart back into an appropriate cardiac rhythm.

11. If an implanted ICD and lead operate properly, the system can save a patient's life. If either fails to operate, the patient may die within minutes.

THE SPRINT FIDELIS LEADS

12. This Class Action seeks recovery for residents and citizens of the State of California who are patients who have been implanted with Sprint Fidelis leads marketed by Medtronic under the following model numbers:

(i) the 6949 LFJ extendable/retractable screw fixation (S) model;

(ii) the 6948 LFH tuned fixation (T) model;

(iii) the 6931 LFT S fixation; and

(iv) the 6930 LFK T fixation.

13. At all times relevant, these Sprint Fidelis leads were researched, developed, manufactured, marketed, promoted, advertised, sold, and distributed by Medtronic to be used in connection with ICDs.

14. The majority of ICDs now use two or three leads. As a result, smaller high-voltage leads are attractive to electrophysiologists because they are believed to be easier to insert, and are less likely to obstruct blood flow or distort the tricuspid valve. The Medtronic Sprint Fidelis leads are smaller high voltage leads.

15. In 2001, Medtronic marketed its then-smallest defibrillation lead called the Sprint Quattro Secure, model 6947 ("Quattro leads").

16. In 2004, Medtronic introduced and marketed the Sprint Fidelis to replace the Sprint Quattro as the high voltage lead of choice and to attempt to gain a larger market share.

17. At the time that Medtronic announced the marketing of the Sprint Fidelis leads, Medtronic claimed that "[t]he small size of the Sprint Fidelis (Fidelis is a Latin word that means 'faithful') helps improve passage into a patient's venous system for an easier implant, and minimizes venous obstruction." Medtronic also referred to the leads as "state-of-the-art." *See* Medtronic News Release (Sept. 2, 2004), available at http://wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1095281834568&lang=en_US.

18. Medtronic further represented that the Sprint Fidelis leads were based on the "proven" design of the Quattro leads.

19. The Sprint Fidelis leads were approved for sale by the United States Food and Drug Administration (the "FDA") in September 2004 and have been implanted in over 160,000 patients worldwide.

20. The Sprint Fidelis lead is a 6.6 French[1] isodiametric multifilar true bipolar high voltage lead with silicone insulation and polyurethane outer coating.

21. The Models 6949 and 6948 have two high voltage coils; the 6930 and 6931 models have a single right ventricular high voltage coil. As of January 2007, at least 144,311 model 6949 Sprint Fidelis leads, 7510 model 6948 leads, 5387 model 6931 leads, and 236 model 6930 leads had been implanted.

THE DEFECTS IN THE SPRINT FIDELIS LEADS

22. Since the Sprint Fidelis leads were introduced to the market, it has become evident that a significant portion of the leads have potentially fatal defects.

23. Such defects were discussed in an article written by doctors at The Minneapolis Heart Institute, one of the premiere heart institutes in the world, based on a study of the incidence of lead failures in the Sprint Fidelis models compared to the Sprint Quattro models. According to the report, which was prepared by Dr. Robert G. Hauser, *et al.*, and published in the Heart Rhythm Society Journal in the Spring of 2007, "Early Failure of Small-Diameter High-Voltage Inflammable Cardioverter-Defibrillator Lead," Heart Rhythm Society 2007.03.041 (2007) ("Early Failure"), the Minneapolis Heart Institute's experience reflected that, between September 2004 and February 2007, 583 patients were implanted with Sprint Fidelis Model 6949 leads, and nine patients received other Sprint Fidelis models. During that time, six patients experienced Sprint Fidelis Model 6949 lead failures. The failed Sprint Fidelis Model 6949 leads had been implanted by various electrophysiologists, cardiologists and thoracic surgeons. The average time to failure was fourteen months (based on a range of four to twenty-three months). *Early Failure*, p. 893.

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[1] French is a measure of circumference in this instance. One French is equal to 0.33 mm, or approximately 0.012 inches.

24. The study compared the actuarial survival of the 583 Sprint Fidelis Model 6949 leads implanted at the Minneapolis Heart Institute to the survival of 285 Sprint Quattro Model 6947 leads implanted at the Institute between November 2001 and March 2007. The difference in survival between the Sprint Fidelis Model 6949 lead and the Sprint Quattro Secure Model 6947 lead was extremely significant. The failure rate for the Sprint Fidelis Model 6949 lead was 1-2% during the first two years of implant and was ten times greater than the failure rate for the Sprint Quattro Secure Model 6947 lead. *Early Failure*, p. 893-894

25. The significant number of lead failures involved lead fractures of the PACE-sense conductor or coil in the Sprint Fidelis Model 6949. The fracture rate for the Sprint Fidelis leads was three times higher than the fracture rate of the Quattro Model 6947. *Early Failure*, p. 894-895.

26. Another study, conducted at Cornell University Medical Center by Sunil Mirchandani, *et al.*, found "(a) 17% incidence of abnormal right ventricular sensing during follow-up of patients implanted with the Medtronic Sprint Fidelis ICD lead," necessitating "an early revision of the system in 4% of patients." *See* Abstract of *Defibrillator Leads: Is Smaller Necessarily Better?*, 2006, available at http://vivo.library.cornell.edu/entity.

27. Medtronic has not disclosed the precise mechanism of the Sprint Fidelis lead fracture failures. However, it appears that the defect in the Sprint Fidelis may be attributable to the small diameter of the coil and conductors and the fact that, in light of this small diameter, it is subject to stress damage both during and after implant. Fracture eventually occurs when the conductor is critically overstressed. The number of fractures that have been observed in these leads indicates that there is a clear defect in the leads themselves, and that defect was demonstrated in the Model 6949 Sprint Fidelis leads that were implanted in Plaintiff Rashid Hunter. Further, Plaintiff Rashid Hunter and Class members who, like Plaintiff Mr. Hunter were implanted with Sprint Fidelis leads, require ongoing and expensive medical monitoring of their Sprint Fidelis leads.

28. A review of the FDA's MAUDE database, which contains reports of adverse events associated with the use of medical devices, discloses that, as of July 2007, over

1000 Medical Device Reports ("MDRs) regarding Sprint Fidelis leads had been filed since September 2004. The most frequent complaints were fractures and inappropriate shocks, and the most common observations were high impedance, oversensing and noise, and failure to capture or high threshold.

29. Medtronic analyzed approximately 125 of those leads that were returned to Medtronic before July 2006. According to the relevant MDR reports, Medtronic concluded that 77 out of 125 leads (or 62%) were defective. The predominant manifestation of the defect was conductor fracture, involving the PACE-sense conductor and coil or the high voltage (defibrillation) conductor. PACE-sense conductor or coil fracture was manifested by inappropriate shocks or oversensing/noise and high impedance, while high voltage conductor fracture was primarily linked to high impedance

30. Medtronic filed more than 350 additional MDRs regarding the Sprint Fidelis leads between August 2006 and February 2007. Medtronic did not include similar analysis of those leads in the MDRs filed by Medtronic during this period.

31. On March 21, 2007, Medtronic issued a physician advisory, in the nature of a "Dear Doctor Letter," that advised physicians of "the higher than expected conductor fracture rates in … Sprint Fidelis leads." Medtronic claims in that letter to be investigating reports of lead failures, however, still represents that the Sprint Fidelis leads are performing consistent with, and "in line with other Medtronic leads …. And consistent with lead performance publicly reported by other manufacturers." This letter also states, "…variables within the implant procedure may contribute significantly to these fractures… For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area." At no time prior to this letter did Medtronic warn physicians that its leads must be specially handled during the implantation procedure or that they could "severely bend" or "kink" if they are implanted using certain accepted implant techniques.

32. On October 15, 2007, Medtronic voluntarily withdrew all unimplanted Sprint Fidelis leads from the U.S. market, citing several deaths related to the leads. Medtronic

stated that approximately 268,000 Sprint Fidelis leads have been implanted worldwide. Medtronic recommended that implanted Sprint Fidelis leads be monitored and reprogrammed.

33. Medtronic has recommended medical monitoring and reprogramming of the ICDs to monitor the Sprint Fidelis leads, according to an article in the October 15, 2007 *Wall Street Journal*, "Medtronic Pulls Defibrillator Wires Off Market."

34. Medtronic's representation of the consistency of the performance of the Sprint Fidelis leads is untrue in light of the reported experience with the leads and the various issues included in the MAUDE database reports.

35. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis leads and negligently manufactured, marketed, advertised, promoted, sold, and distributed the leads as safe devices to be used together with ICDs for prophylactic treatment of patients with prior myocardial infarction and decreased ejection fraction, ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias. Some patients are dependent on such devices to maintain an appropriate heart rhythm, and therefore, adequate cardiac output. For these patients, failure of the leads connected to the ICD can cause sudden faintness, or loss of consciousness, and can result in death.

36. At all times relevant, Medtronic failed to warn that the Sprint Fidelis leads were prone to breakage or that particular processes should be implemented in order to avoid breaking the Sprint Fidelis leads.

37. As a result of their defective design and manufacture, Medtronic's Sprint Fidelis leads suffer fracture, leading to malfunction in the transmission of the electric signal from the ICD to the patient's heart.

38. At all times relevant, the Sprint Fidelis leads (collectively the "leads") were researched, developed, manufactured, marketed, promoted, advertised and sold by Medtronic.

39. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis leads, and negligently manufactured, marketed, advertised, promoted, sold and distributed the leads as safe and effective devices to be used for implantation with ICDs for prophylactic treatment of patients with prior myocardial infarction and a limited ejection fraction, patients who

have had spontaneous and/or inducible life-threatening ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias.

40. At all times relevant, Medtronic knew, and had reason to know, that the Sprint Fidelis leads were not safe for the patients for whom they were prescribed and implanted, because the leads fractured and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some patients, catastrophic injuries and deaths.

41. At all times relevant, Medtronic knew, and had reason to know, that its representations that the Sprint Fidelis leads were easier to implant and based on "proven" technology were materially false and misleading.

42. As a result of this defective design and manufacture, the leads can cause serious physical trauma and/or death. Medtronic knew and had reason to know of this tendency and the resulting risk of injuries and deaths, but concealed this information and did not warn Plaintiff, the Class members or their physicians, preventing Plaintiff, the Class members and their physicians, and the medical community from making informed choices about the selection and use of particular defibrillator leads for implantation.

43. Approximately 268,000 of the affected devices remain in service in the United States and in other countries.

44. Medtronic has records of all patients with implanted leads, and can identify all members of the class of California state residents and citizens with implanted and defective leads who require medical monitoring.

45. The information Medtronic has made available to patients and their doctors about the need for medical monitoring, the types of available monitoring, and the costs incident to such monitoring are extremely inconsistent and confusing.

46. Plaintiff seeks implementation of a medical monitoring program to be administered by this Court, which will afford each California state lead recipient with consistent monitoring paid for by Defendants.

47. Plaintiff now brings this action to seek injunctive relief or an expedited trial pursuant to Rule 65 of the Federal Rules of Civil procedure to adjudicate his claims against Medtronic and to implement a medical monitoring program immediately.

JURISDICTION AND VENUE

48. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because this action is a class action that includes parties and Class members who are citizens of different states and the matter in controversy exceeds the sum or value of $5,000,000 exclusive of interest and costs.

49. Venue is proper under 28 U.S.C. §§ 1391 (a) and (c). Medtronic earns substantial compensation and profits from sales of Sprint Fidelis leads in this District.

INTRADISTRICT ASSIGNMENT

50. Assignment of this matter to the San Francisco/Oakland Division of this Court is proper pursuant to L.R. 3-2(c) and (d), because Mr. Hunter resides in Alameda County and the action arises in Alameda County.

CLASS ACTION ALLEGATIONS

51. Plaintiff brings this action on behalf of himself and all others similarly situated, as members of a proposed Plaintiff class (the "Class") of all individuals who have been implanted with the leads at issue, and propose a California Class, composed of:

> All citizens and residents of the State of California who have been implanted with Sprint Fidelis leads marketed by Medtronic under the following model numbers: (1) the 6949 LFJ extendable/retractable screw fixation (S) model; (2) the 6948 LFH tuned fixation (T) model; (3) the 6931 LFT S fixation; and (4) the 6930 LFK T fixation, manufactured by Medtronic ("patient recipients"), during the period from January 1, 2004 through the present (the "Class period"), and their legal guardians or representatives.

52. Excluded from the proposed subclass are (i) Medtronic, any entity in which Medtronic has a controlling interest or which have a controlling interest in Medtronic, and Medtronic's legal representatives, predecessors, successors and assigns; (ii) the judicial officers to whom this case is assigned; and (iii) any member of the immediate families of excluded persons.

53. The Class is so numerous that the individual joinder of all its members is impracticable. While the exact number and identification of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery of Medtronic, Plaintiff is informed and believes that the Class includes thousands of patient recipients statewide.

54. This action is brought and may properly be maintained as a class action pursuant to the provisions of Federal Rule of Civil Procedure 23(a)(1)-(4), 23(b)(2), and 23(b)(3) and/or 23(c)(4)(A). This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions. Common questions of fact and law exist as to all Class members which predominate over any questions affecting only individual Class members. These common legal and factual questions, which do not vary from Class member to Class member, and which may be determined without reference to the individual circumstances of any Class member, include, but are not limited to, the following:

(a) Whether there are design and/or manufacturing defects in Medtronic's Sprint Fidelis leads;

(b) Whether Medtronic failed to follow United States Food & Drug Administration ("FDA") good manufacturing practices, failed to properly investigate manifestations of the lead defects over the past several years, failed to adequately document reports of the defects, and failed to exercise adequate quality control;

(c) Whether Medtronic's conduct in designing, manufacturing, marketing, and monitoring the Sprint Fidelis leads fell below the duty of care owed by Medtronic to Plaintiff and the other Class members;

(d) Whether Medtronic intentionally, deliberately, uniformly, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed and suppressed material and important information regarding the existence of a defect in the Sprint Fidelis leads from Plaintiff, the FDA, physicians and Class members;

(e) Whether the Sprint Fidelis leads listed in the proposed Class definition share common and inherent design and manufacturing defects that cause them to fracture and malfunction, causing inappropriate shocks and failure to deliver an effective shock when needed, creating a risk of injury or death to patients in whom they were implanted;

(f) Whether Medtronic negligently, intentionally, deliberately, uniformly, or recklessly materially misrepresented, concealed, omitted, or suppressed the quality and usefulness of the leads, thereby inducing Plaintiff and the Class to accept implantation of the Sprint Fidelis leads rather than another brand of leads, which would not have been prone to the defects;

(g) Whether Medtronic is liable for selling a dangerously defective product;

(h) Whether Medtronic failed to adequately warn or notify patient recipients, the medical community, and the regulators of the defect, dangers, disadvantages and hazards of the leads;

(i) Whether Medtronic failed to adequately warn or notify hospitals and physicians regarding the defect, malfunction and/or hazards of the defective leads;

(j) Whether Medtronic breached express or implied warranties;

(k) Whether Medtronic's conduct constitutes negligence;

(l) Whether Medtronic is liable for negligent infliction of emotional distress;

(m) Whether Medtronic's misconduct violated applicable consumer protection statutes;

(n) Whether Plaintiff and Class members are entitled to injunctive and other equitable relief, including restitution and disgorgement, and if so, the nature of such relief;

(o) Whether Plaintiff and Class members are entitled to medical monitoring, reprogramming, surveillance and medical treatment at Medtronic's expense;

(p) Whether Medtronic is liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish them for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages; and,

(q) Which mechanism, among the methods available under the Federal Rules of Civil Procedure, is superior to ensure the fair and efficient adjudication of this controversy within the meaning of Fed. R. Civ. P. 23(b)(3).

55. Plaintiff's claims are typical of the claims of the Class members. Plaintiff and other Class members must prove the same facts in order to establish the same claims, described herein, which apply to all Class members.

56. Plaintiff is an adequate representative of the Class because he is a member of the Class and his interests do not conflict with the interests of the Class members he seeks to represent. Plaintiff has retained counsel competent and experienced in the prosecution of products liability, mass torts, and consumer fraud class actions, and together Plaintiff and counsel intend to prosecute this action vigorously for the benefit of the Class. The interests of Class members will fairly and adequately be protected by Plaintiff and their counsel.

57. A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual litigation of the claims of all Class members is impracticable. Even if every Class member could afford individual litigation, the court system could not. It would be unduly burdensome to the courts, in which individual litigation of thousands of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, the prospect of a race for the courthouse, and an inequitable allocation of recovery among those with equally meritorious claims. Individual litigation increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all Medtronic Sprint Fidelis lead claims. By contrast, the class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

58. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Federal Rules of Civil Procedure 23(b)(1) and/or 23(b)(2) because:

(a) The prosecution of separate actions by thousands of individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Medtronic;

(b) The prosecution of separate actions by individual Class members would also create the risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of the other Class members who are not a party to such adjudications and would substantially impair or impede the ability of such non-party Class members to protect their interests;

(c) Medtronic has acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and injunctive relief with respect to the Class as a whole.

ALLEGATIONS

59. Medtronic designed, manufactured, marketed, promoted, sold, and distributed four (4) models of defective leads, including: (1) the Sprint Fidelis 6949 LFJ extendable/retractable screw fixation (S) model; (2) the 6948 LFH tuned fixation (T) model; (3) the 6931 LFT S fixation model; and (4) the 6930 LFK fixation (T) model. All of the these models contain the same defect.

60. The Sprint Fidelis leads were originally approved for sale by the FDA in September 2004.

61. The Sprint Fidelis leads are uniformly defective in that they are prone to fracture of the PACE-sense conductor and coil and the HV conductor, causing them to fail to function in a manner which may not be immediately detectable by the patient. The

malfunctioning can lead to terrifying inappropriate defibrillation shocks, failure to deliver appropriate (life-giving) defibrillation therapy and death.

62. There is no test that predicts whether the Sprint Fidelis leads will fail.

63. To this day, Medtronic has refused to suggest replacement of the defective Sprint Fidelis leads in its patients, even though emergency replacement of the leads is required in patients in whom these defects have been discovered.

A. Medtronic's Concealment of the Defects

64. Medtronic's failure to document or follow up on the known defects in its Sprint Fidelis leads, and concealment of known defects from the FDA, Plaintiff, the medical community and Class members constitutes fraudulent concealment that equitably tolls any applicable statute of limitation.

65. No member of the Class could have discovered the existence of the defect in the Sprint Fidelis leads until at least March 2007, when the first physician advisory was sent by Medtronic to physicians concerning the fragile nature of these leads.

66. Medtronic is estopped from relying on the statute of limitations as a defense because Medtronic actively concealed the lead defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians or Class members. Instead of revealing the defects, Medtronic continued to represent its products as safe for their intended use.

67. Medtronic's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Medtronic must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff and Class members.

B. Medtronic's Failure to Provide Adequate and Accurate Information

68. Thousands of patients' lives rely upon the proper functioning of these Sprint Fidelis leads, and they — along with their physicians — have been vigorously attempting to assess the risks that they now face.

69. Patients and physicians remain uninformed and confused about whether the devices should be removed, or even whether all of the defects have been disclosed.

70. Because of incomplete, inconsistent, and/or confusing information published by Medtronic, it remains unclear how many patients are affected by these defective leads. Although, based on the population of Medtronic patients whose claims are asserted in this Complaint, it is likely to be thousands of heart patients in the State of California.

C. Corporate Liability

71. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiff.

72. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

73. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

74. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and

promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

D. Medical Monitoring

75. On October 15, 2007, Medtronic publicly advised all patients with their leads that medical monitoring of their leads was advisable.

76. On October 22, 2007, Medtronic sent form letters to each of the patients and Class members with defective leads. To date, Medtronic sent letters to 175,000 patients with Sprint Fidelis leads and the hospitals and doctors, who had implanted these leads. In those letters, Medtronic advised patients, like Mr. Hunter, to seek advice from their physicians so that their devices could be monitored and reprogrammed. The information made available to Mr. Hunter and others Class members is, however, both confusing and frightening, because the failure of the leads is not predictable.

PLAINTIFF

77. Plaintiff Rashid Hunter has a cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. Mr. Hunter was implanted with a cardiac pacemaker/defibrillator combination (an "ICD") on January 17, 2005, at Washington Hospital Healthcare System in Fremont, California. The ICD was attached to his heart with a lead wire system called a Sprint Fidelis lead, model number 6949, manufactured by Medtronic.

78. As a result of the Medtronic advisory, it is clear that Mr. Hunter's 6949 must be closely monitored.

79. Mr. Hunter has suffered and will continue to suffer severe emotional damages and has incurred, and will in the future continue to incur medical expenses and losses, including the need for an expense of ongoing medical monitoring, as a result of Medtronic's wrongful conduct.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
(Products Liability)

80. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

81. At all relevant times hereto, Medtronic was engaged in the business of designing, manufacturing, assembling, promoting, advertising, selling, and distributing the Sprint Fidelis leads for ultimate sale to, and implantation in, heart disease/disorder patients. Medtronic designed, manufactured, assembled, and sold the Sprint Fidelis leads to hospitals and physicians, knowing that they would be thereby sold to patients with heart diseases and disorders (including Plaintiff and Class members) and implanted in those patients.

82. Medtronic's Sprint Fidelis leads were expected to and did reach Plaintiff and the Class without substantial change in their condition as manufactured and sold by Medtronic. In light of the defects described herein, at the time the leads reached Plaintiff and the Class, they were in a condition not contemplated by any reasonable person among the expected users of the devices, and were unreasonably dangerous to the expected users of the devices when used in reasonably expectable ways of handling or consumption.

83. The Sprint Fidelis leads designed, manufactured, assembled, and sold by Medtronic to Plaintiff and Class members were in a defective condition unreasonably dangerous to any user or consumer of the devices, and Plaintiff and Class members were, and are, in the class of persons that Medtronic should reasonably have foreseen as being subject to the harm caused by the devices' defective condition.

84. Plaintiff and Class members used the leads in the manner in which the leads were intended to be used. This has resulted in injuries to Plaintiff and Class members.

85. Neither Plaintiff nor Class members were aware of, and could not in the exercise of reasonable care have discovered, the defective nature of Medtronic's Sprint Fidelis leads. Nor could they have known that Medtronic designed, manufactured or assembled the leads in a manner that would increase the risk of bodily injury to Plaintiff and the Class.

86. As a direct and proximate result of Medtronic's design, manufacture, assembly, marketing and sales of the Sprint Fidelis leads, Plaintiff and the Class members have sustained and will continue to sustain severe emotional distress, the need for an expense of ongoing medical monitoring, economic losses and consequential damages, and are therefore entitled to compensatory relief according to proof, and entitled to a declaratory judgment that Medtronic is liable to them for breach of its duty to Plaintiff and the Class members and its failure to provide a safe and effective medical device. Plaintiff and the Class members are also entitled to equitable relief as described below.

87. Medtronic's Sprint Fidelis leads constitute a product dangerous for its reasonably intended use due to defective design, manufacture, assembly and marketing. Medtronic is therefore liable to Plaintiff and Class members to pay the costs of a court-supervised medical monitoring program to detect fractured or malfunctioning leads before they cause further injury and damage in an amount according to proof.

SECOND CLAIM FOR RELIEF
(Breach of Implied Warranty)

88. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

89. Medtronic impliedly warranted that its Sprint Fidelis leads, which Medtronic designed, manufactured, assembled, promoted and sold to Plaintiff and Class members, were merchantable and fit and safe for ordinary use. Medtronic further impliedly warranted that its Sprint Fidelis leads were fit for the particular purpose of providing prophylactic treatment of patients with a variety of medical issues, including prior myocardial infarction and a limited ejection fraction, spontaneous and/or inducible life-threatening ventricular arrhythmias and a high risk for developing such arrhythmias.

90. Medtronic further impliedly warranted that its Sprint Fidelis leads were based on "proven" lead technology and that the Sprint Fidelis leads were easier to implant than others.

91. Medtronic's Sprint Fidelis leads were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiff and Class members to the threat of severe and permanent injuries and death. Therefore, Medtronic breached the implied warranties of merchantability and fitness for a particular purpose when its leads were sold to Plaintiff and Class members, in that the leads are defective and have fractured and will, more likely than not, fail to function as represented and intended.

92. As a direct and proximate result of Medtronic's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff and Class members have sustained and will continue to sustain severe emotional distress, the need for and expense of ongoing medical monitoring, economic losses and consequential damages, and are therefore entitled to compensatory damages and equitable relief according to proof.

THIRD CLAIM FOR RELIEF
(Negligence)

93. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

94. Medtronic had a duty to Plaintiff and Class members to provide a safe product in design and manufacture, to notify the FDA of design flaws, and to warn the FDA and Class members of the defective nature of the Sprint Fidelis leads. Medtronic breached its duty of reasonable care to Plaintiff and Class members by incorporating a defect into the design of the Sprint Fidelis leads, thereby exposing Plaintiff and Class members to severe physical injury or death, and causing severe emotional distress, economic injury and the need for and expense of ongoing medical monitoring, as well as other injury.

95. Medtronic breached its duty of reasonable care to Plaintiff and Class members by manufacturing and assembling the Sprint Fidelis leads in such a manner that they were prone to fracture, to fail to operate and to malfunction, thereby exposing Plaintiff and Class members to life-threatening physical trauma.

96. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to notify the FDA, physicians, the Plaintiff and the Class members at the earliest possible date of known design defects in the leads.

97. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to exercise due care under the circumstances.

98. As a direct and proximate result of Medtronic's negligent breach of its duty of care owed to Mr. Hunter and the Class members, Mr. Hunter and the Class members are currently exposed to a defective product which threatens them with severe physical injury and death.

99. Plaintiff and the Class members have a serious and reasonable fear, which stems from knowledge corroborated by reliable medical and/or scientific opinion, that they more likely than not will suffer severe physical injury or death in the future as the result of the implantation of the defective Sprint Fidelis leads.

100. As a direct and proximate result of the carelessness and negligence of Medtronic as set forth in the preceding paragraphs, Plaintiff and Class members have sustained and will continue to sustain severe emotional distress, the need for and expense of ongoing medical monitoring, economic losses and other damages, and are entitled to compensatory damages and equitable and declaratory relief according to proof. Medtronic's egregious misconduct alleged above also warrants the imposition of punitive damages against Medtronic.

FOURTH CLAIM FOR RELIEF
(Negligent Infliction of Emotional Distress)

101. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

102. Medtronic carelessly and negligently manufactured, marketed and sold defective Sprint Fidelis leads to Plaintiff and Class members, carelessly and negligently concealed these defects from Plaintiff and Class members, and carelessly and negligently misrepresented the quality, safety and usefulness of the leads.

103. Medtronic had a duty to Plaintiff and Class members to provide a safe product in design and manufacture, to notify the FDA of design flaws, and to warn the FDA and Class members of the defective nature of the Sprint Fidelis leads. Medtronic breached its duty of reasonable care to Plaintiff and Class members by incorporating a defect into the design of the Sprint Fidelis leads, thereby causing Plaintiff's and Class members' injuries.

104. Medtronic breached its duty of reasonable care to Plaintiff and Class members by manufacturing and assembling the Sprint Fidelis leads in such a manner that they were prone to fracture and fail to operate and malfunction and expose Plaintiff and Class members to life-threatening physical trauma.

105. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to notify the FDA, physicians, the Plaintiff and the Class members at the earliest possible date of known design defects in the leads.

106. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to exercise due care under the circumstances.

107. As a direct and proximate result of Medtronic's negligent breach of its duty of care owed to Mr. Hunter and the Class members, Mr. Hunter and the Class members are currently exposed to a defective product which threatens them with severe physical injury and death.

108. Plaintiff and the Class members have a serious and reasonable fear, which stems from knowledge, corroborated by reliable medical and/or scientific opinion, that they more likely than not will suffer severe physical injury or death in the future as the result of the implantation of the defective Sprint Fidelis leads.

109. Plaintiff and Class members were directly involved in and directly impacted by Medtronic's carelessness and negligence, in that Plaintiff and Class members have sustained and will continue to sustain severe emotional distress, economic losses, the need for and expense of ongoing medical monitoring and other damages as a direct result of the decision to purchase, use and have implanted in their bodies a defective and dangerous product manufactured, sold and distributed by Medtronic.

110. Medtronic's misconduct as alleged above has caused Plaintiff and Class members to suffer severe emotional trauma and long continued emotional disturbance. Plaintiff and Class members are therefore entitled to compensatory damages and equitable and declaratory relief according to proof.

FIFTH CLAIM FOR RELIEF
(Breach of Express Warranties)

111. Plaintiff, on behalf of himself and all others similarly situated, re-alleges and incorporates the allegations contained in the foregoing paragraphs.

112. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, the internet, and other communications intended for medical patients, and the general public, that the defective leads were safe, effective, fit and proper for their intended use.

113. In allowing the implantation of the defective leads, Plaintiff relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the defective leads were not safe and were unfit for the uses for which they were intended.

114. Through its sale of the defective leads, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

115. Any disclaimers of express warranties are ineffectual as they were not provided to Plaintiff or the Class members or otherwise made known totem. In addition, any such disclaimers are unconscionable.

116. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff and the Class members have sustained economic losses, the need for and expense of ongoing medical monitoring and other damages for which he is entitled to compensatory damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and damages to Plaintiff and the Class members in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential

damages in unconscionable. Defendants are liable to Plaintiff and the Class members jointly and severally for all declaratory, equitable and injunctive relief, including the costs of a court-supervised medical monitoring program, and for all damages to which Plaintiff is entitled by law.

FIFTH CLAIM FOR RELIEF
(Violation of Unfair Competition Law ("UCL"), Bus. & Prof. Code §§ 17200, *et seq.*)

117. Plaintiff, on behalf of himself and all others similarly situated, realleges and incorporates the allegations contained in the foregoing paragraphs

118. The UCL prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising" as that term is used in Business and Professions Code § 17500.

119. In violating the California Business and Professions Code §§ 17200, *et seq.*, as set forth above as the Fifth Cause of Action and incorporated herein, Medtronic engaged in unlawful business practices in violation of the UCL.

120. Medtronic engaged in unfair business practices in violation of the UCL. The benefits of its practice of selling defective Spirit Fidelis leads that are inherently dangerous and unreasonably prone to malfunction are outweighed by the resulting harm and danger to Plaintiff, the Class, and the public.

121. Medtronic engaged in fraudulent business acts or practices in that it actively concealed material information about the safety of the defective Spirit Fidelis leads and it engaged in marketing which was likely to deceive the Plaintiff, the Class, physicians and the public.

122. Medtronic engaged in unfair competition or unlawful, unfair or fraudulent business practices in violation of the UCL when it represented, through its marketing, warranties and other express representations that the defective Spirit Fidelis leads were safe and free from defects.

123. As a proximate result of its unlawful, unfair or fraudulent practices, Medtronic has been unjustly enriched and should be required to make restitution and/or disgorgement of profits unjustly earned to the Plaintiff and the Class pursuant to Sections 17203

and 17204 of the UCL and/or provide other appropriate equitable relief, including a court-supervised medical monitoring program.

SIXTH CLAIM FOR RELIEF
(Declaratory Relief and Medical Monitoring)

124. Plaintiff, on behalf of himself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

125. Plaintiff and Class members have no adequate remedy at law and damages cannot adequately compensate Plaintiff and Class members for the injuries suffered and threatened, rendering declaratory, injunctive, and other equitable relief appropriate.

126. Through the unlawful conduct set forth in the preceding paragraphs, Plaintiff and thousands of Class members have been implanted with a device which tends to fracture, and otherwise malfunction. These defects have potentially fatal consequences for many patients who rely upon the presence of the leads connected to the ICDs to regulate their cardiac rhythms. These defects place Plaintiff and Class members at significant, increased risk of injury and death, as a direct result of their implantation with said leads, through Defendants' fault. These risks are unique to the Class, and detectable and correctable through ongoing medical monitoring.

127. There are medical risks to Plaintiff and Class members associated with having the defective Sprint Fidelis leads explanted, as they have been implanted directly onto the heart wall. Explanation procedures expose Plaintiff and Class members to significant risks attendant to surgery, not least of which are potentially life-threatening infections and other harm.

128. At the same time, Plaintiff and Class members, along with their physicians, must weigh these risks against the possibility that Medtronic's Sprint Fidelis leads will fail or have failed to function as designed, represented and intended, resulting in an increased risk of heart damage, failure and/or death.

129. Accordingly, Plaintiff, on behalf of himself and all others similarly situated, requests the following classwide equitable relief:

(a) That Medtronic be ordered to notify all potential Class members of the defective nature of the Sprint Fidelis leads;

(b) That Medtronic be ordered to create a treatment fund, under the continuing jurisdiction and supervision of this Court, to monitor the health of Plaintiff and Class members, and to pay or reimburse Plaintiff and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses caused by Medtronic's wrongdoing; and

(c) Declaratory judgment that Medtronic is liable to Plaintiff and all Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and all others similarly situated, prays for judgment against Medtronic as follows:

1. For an Order certifying the Class and any appropriate subclasses thereof under the appropriate provisions of Federal Rule of Civil Procedure 23, and appointing Plaintiff and his counsel to represent the Class;

2. For the equitable relief requested;

3. For compensatory damages according to proof;

4. For punitive or exemplary damages against Medtronic, consistent with the degree of Medtronic's reprehensibility and the resulting harm or potential harm to Plaintiff and the Class, and in an amount sufficient to punish Medtronic and deter others from similar wrongdoing;

5. For all applicable statutory damages under the consumer protection legislation of the State of California;

6. For declaratory judgment that Medtronic is liable to Plaintiff and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing;

7. For notice to be disseminated to all Class members who have been implanted with Sprint Fidelis leads;

8. For a restitution and disgorgement of profits;

9. For an award of attorneys' fees and costs;

10. For prejudgment interest and the costs of suit; and

11. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff Rashid Hunter, on behalf of himself and all other California state residents and citizens similarly situated, hereby demands a trial by jury in this case as to such issues so triable.

Dated: December 26, 2007

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similarly situated

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

EDL

JENEANE BAQUE, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

MEDTRONIC, INC., a corporation,

Defendant.

CASE NO. C 07 5312

COMPLAINT FOR DAMAGES AND EQUITABLE RELIEF

CLASS ACTION

DEMAND FOR JURY TRIAL

PREAMBLE

Plaintiff JENEANE BAQUE, by her undersigned counsel, for herself and all others similarly situated, hereby commences this individual and Class Action against Medtronic, Inc., (hereinafter collectively "Defendant" or "Medtronic," unless otherwise stated) for compensatory,

equitable, injunctive, and declaratory relief. Plaintiff makes the following allegations based upon her personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Medtronic's actions and misconduct, and alleges as follows:

PARTIES

1. Individual and representative Plaintiff Jeneane Baque is a citizen and resident of the State of California.

2. Defendant Medtronic, Inc is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Medtronic develops technology to treat conditions such as heart disease and other illnesses. Medtronic manufactures medical devices throughout the United States, including in the Northern District of California, and sells these devices worldwide. Medtronic's Cardiac Rhythm Disease Management Division ("CRM Division") is the division that develops, researches, advertises, promotes, markets and sells all of Medtronic implantable defibrillators ("ICDs"), and leads, some of which are marketed under the trade name "Sprint Fidelis." CRM Division's operations are principally conducted out of its facilities at Cardiac Rhythm Disease Management at 7000 Central Ave., Minneapolis, Minnesota 55432.

INTRODUCTION

3. Medtronic designs, researches, develops, manufactures, tests, markets, advertises, promotes, distributes, and sells products that treat cardiac arrhythmias, heart failure, and coronary and peripheral vascular disease. An arrhythmia is an irregular cardiac rhythm, which can cause significantly decreased cardiac output and ultimately, death. Medtronic holds itself out as "the global leader in medical technology, alleviating pain, restoring health and extending life for millions of people around the world." (*See* 2005 Annual Statement, Medtronic, Inc.).

4. A number of devices designed to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms are available from Medtronic and other manufacturers, including implantable cardiac defibrillators ("ICDs"). ICDs contain pacemakers as well as defibrillators; while a pacemaker is used primarily to correct slow heart

rates, an ICD detects and corrects both fast and slow heart rates. The pacemaker portion corrects the slow rates and the anti-tachycardia portion can "over-drive pace" rapid rates. The defibrillator portion can shock ventricular tachycardia and ventricular fibrillation to stop the heart and allow an appropriate rhythm to take over.

5. ICDs are designed to be implanted primarily under the skin of the chest wall. The device's power source, or pulse generator, is implanted in a pouch formed in the chest wall generally over the left pectoralis major muscle.

6. Typically, wires called leads are inserted through a major vein and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and can administer an electric shock to abort a dangerous "over-drive pace," a very rapid rhythm, or pace the heart at a normal rhythm if an irregularity is detected.

7. Such devices are used in patients, like Plaintiff, who have arrhythmias or irregular heartbeats that are considered life-threatening. The Class members with these medical problems include patients who are at risk for ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart), ventricular tachycardia (excessively rapid heartbeat) that is poorly controlled by medication. These arrhythmias or irregular heart beats can result in the loss of consciousness or death, unless the patient receives therapy from an appropriate device to put the heart back into an appropriate cardiac rhythm.

8. If an implanted ICD and lead operate properly, the system can save a patient's life. If either fails to operate, the patient may die within minutes.

THE SPRINT FIDELIS LEADS

9. This Class Action seeks recovery for patients who have been implanted with Sprint Fidelis leads marketed by Medtronic under the following model numbers:

(i) the 6949 LFJ extendable/retractable screw fixation (S) model,

(ii) the 6948 LFH tuned fixation (T) model,

(iii) the 6931 LFT S fixation, and,

(iv) the 6930 LFK T fixation.

10. At all times relevant, these Sprint Fidelis leads were researched, developed, manufactured, marketed, promoted, advertised, sold, and distributed by Medtronic to be used in connection with ICDs.

11. The majority of ICDs now use two or three leads. As a result, smaller high-voltage leads are attractive to electrophysiologists because they are believed to be easier to insert, and are less likely to obstruct blood flow or distort the tricuspid valve. The Medtronic Sprint Fidelis leads are smaller high voltage leads.

12. In 2001, Medtronic marketed its then-smallest defibrillation lead called the Sprint Quattro Secure, model 6947 ("Quattro leads").

13. In 2004, Medtronic introduced and marketed the Sprint Fidelis to replace the Sprint Quattro as the high voltage lead of choice and to attempt to gain a larger market share.

14. At the time that Medtronic announced the marketing of the Sprint Fidelis leads, Medtronic claimed that "[t]he small size of the Sprint Fidelis (Fidelis is a Latin word that means 'faithful') helps improve passage into a patient's venous system for an easier implant, and minimizes venous obstruction." In a News Release dated September 2, 2004, Medtronic also referred to the leads as "state-of-the-art."

15. Medtronic further represented that the Sprint Fidelis leads were based on the "proven" design of the Quattro leads.

16. The Sprint Fidelis leads were approved for sale by the United States Food and Drug Administration (the "FDA") in September 2004 and have been implanted in over 160,000 patients worldwide.

17. The Sprint Fidelis lead is a 6.6 French isodiametric multifilar true bipolar high voltage lead with silicone insulation and polyurethane outer coating.

18. The Models 6949 and 6948 have two high voltage coils; the 6930 and 6931 models have a single right ventricular high voltage coil. As of January 2007, approximately 144,311 model 6949 Sprint Fidelis leads, 7510 model 6948 leads, 5387 model 6931 leads, and 236 model 6930 leads had been implanted.

THE DEFECTS IN THE SPRINT FIDELIS LEADS

19. Since the Sprint Fidelis leads were introduced to the market, it has become evident that a significant portion of the leads have potentially fatal defects.

20. Such defects were discussed in an article written by doctors at The Minneapolis Heart Institute, one of the premiere heart institutes in the world, based on a study of the incidence of lead failures in the Sprint Fidelis models compared to the Sprint Quattro models. According to the report, which was prepared by Dr. Robert G. Hauser, *et al.*, and published in the *Heart Rhythm Society Journal* in the Spring of 2007, "Early Failure of Small-Diameter High-Voltage Inflammable Cardioverter-Defibrillator Lead", Heart Rhythm Society 2007.03.041 (2007) ("Early Failure"), the Minneapolis Heart Institute's experience reflected that, between September 2004 and February 2007, 583 patients were implanted with Sprint Fidelis Model 6949 leads, and nine patients received other Sprint Fidelis models. During that time, six patients experienced Sprint Fidelis Model 6949 lead failures. The failed Sprint Fidelis Model 6949 leads had been implanted by various electrophysiologists, cardiologists and thoracic surgeons. The average time to failure was fourteen months (based on a range of four to twenty-three months). *Early Failure*, p. 893.

21. The study compared the actuarial survival of the 583 Sprint Fidelis Model 6949 leads implanted at the Minneapolis Heart Institute to the survival of 285 Sprint Quattro Model 6947 leads implanted at the Institute between November 2001 and March 2007. The difference in survival between the Sprint Fidelis Model 6949 lead and the Sprint Quattro Secure Model 6947 lead was extremely significant. The failure rate for the Sprint Fidelis Model 6949 lead was 1-2% during the first two years of implant and was ten times greater than the failure rate for the Sprint Quattro Secure Model 6947 lead. *Early Failure*, p. 893-894.

22. The significant number of lead failures involved lead fractures of the PACE-sense conductor or coil in the Sprint Fidelis Model 6949. The fracture rate for the Sprint Fidelis leads was three times higher than the fracture rate of the Quattro Model 6947. *Early Failure*, p. 894-895.

23. Another study, conducted at Cornell University Medical Center by Sunil Mirchandani, *et al.*, found "(a) 17% incidence of abnormal right ventricular sensing during follow-up of patients implanted with the Medtronic Sprint Fidelis ICD lead," necessitating "an early revision of the system in 4% of patients."

24. Medtronic has not disclosed the precise mechanism of the Sprint Fidelis lead fracture failures. However, it appears that the defect in the Sprint Fidelis may be attributable to the small diameter of the coil and conductors and the fact that, in light of this small diameter, it is subject to stress damage both during and after implant. Fracture eventually occurs when the conductor is critically overstressed. The number of fractures that have been observed in these leads indicates that there is a clear defect in the leads themselves, and that defect was demonstrated in the 6949 leads that were implanted in Plaintiff Jeneane Baque. Plaintiff Baque requires medical monitoring of her 6949 leads.

25. A review of the FDA's MAUDE database, which contains reports of adverse events associated with the use of medical devices, discloses that, as of July 2007, over 1000 Medical Device Reports ("MDR"s) regarding Sprint Fidelis lead had been filed since September 2004. The most frequent complaints were fracture and inappropriate shocks, and the most common observations were high impedance, over-sensing and noise, and failure to capture or high threshold.

26. Medtronic analyzed approximately 125 of those leads that were returned to Medtronic before July 2006. According to the relevant MDR reports, Medtronic concluded that 77 out of 125 leads (or 62%) were defective. The predominant manifestation of the defect was conductor fracture, involving the PACE-sense conductor and coil or the high voltage (defibrillation) conductor. PACE-sense conductor or coil fracture was manifested by inappropriate shocks or over-sensing/noise and high impedance, while high voltage conductor fracture was primarily linked to high impedance.

27. Medtronic filed more than 350 additional MDRs regarding the Sprint Fidelis leads between August 2006 and February 2007. Medtronic did not include similar analysis of those leads in the MDRs filed by Medtronic during this period.

28. On March 21, 2007, Medtronic issued a physician advisory, in the nature of a "Dear Doctor Letter," that advised physicians of "the higher than expected conductor fracture rates in … Sprint Fidelis leads." Medtronic claims in that letter to be investigating reports of lead failures, however, still represents that the Sprint Fidelis leads are performing consistent with, and "in line with other Medtronic leads …. And consistent with lead performance publicly reported by other manufacturers." This letter also states, "…variables within the implant procedure may contribute significantly to these fractures… For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area." At no time prior to this letter did Medtronic warn physicians that its leads must be specially handled during the implantation procedure or that they could "severely bend" or "kink" if they are implanted using certain accepted implant techniques.

29. On October 15, 2007, Medtronic recalled all unimplanted Sprint Fidelis leads, citing several deaths related to the leads. Medtronic recommended that implanted Sprint Fidelis leads be monitored.

30. Medtronic's representation of the consistency of the performance of the Sprint Fidelis leads is untrue in light of the reported experience with the leads and the various issues included in the MAUDE database reports.

31. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis leads and negligently manufactured, marketed, advertised, promoted, sold, and distributed the leads as safe devices to be used together with ICDs for prophylactic treatment of patients with prior myocardial infarction and decreased ejection fraction, ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias. Some patients are dependent on such devices to maintain an appropriate heart rhythm, and therefore, adequate cardiac output. For these patients, failure of the leads connected to the ICD can cause sudden faintness, or loss of consciousness, and can result in death.

32. At all times relevant, Medtronic failed to warn that the Sprint Fidelis leads were prone to breakage or that particular processes should be implemented in order to avoid breaking the Sprint Fidelis leads.

33. As a result of their defective design and manufacture, Medtronic's Sprint Fidelis leads suffer fracture, leading to malfunction in the transmission of the electric signal from the ICD to the patient's heart.

SUMMARY OF ALLEGATIONS

34. At all times relevant, the Sprint Fidelis (collectively the "leads") were researched, developed, manufactured, marketed, promoted, advertised and sold by Medtronic.

35. At all times relevant, Medtronic misrepresented the safety of the Sprint Fidelis leads, and negligently manufactured, marketed, advertised, promoted, sold and distributed the leads as safe and effective devices to be used for implantation with ICDs for prophylactic treatment of patients with prior myocardial infarction and a limited ejection fraction, patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias.

36. At all times relevant to this action, Medtronic knew, and had reason to know, that the Sprint Fidelis leads were not safe for the patients for whom they were prescribed and implanted, because the leads fractured and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some patients, catastrophic injuries and deaths.

37. At all times relevant to this action, Medtronic knew, and had reason to know, that its representations that the Sprint Fidelis leads were easier to implant and based on "proven" technology were materially false and misleading.

38. Approximately 129,000 of the affected devices remain in service in the United States and in other countries.

39. As a result of this defective design and manufacture, the Sprint Fidelis leads can cause serious physical trauma and/or death. Medtronic knew and had reason to know of this tendency and the resulting risk of injuries and deaths, but concealed this information and did not

warn Plaintiff or their physicians, preventing Plaintiff, the Class and their physicians, and the medical community from making informed choices about the selection of leads for implantation.

JURISDICTION AND VENUE

40. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (d) because this action is a class action that involves parties and class members who are citizens of different states and the value of the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs.

41. The Court also has subject matter jurisdiction pursuant to 28 U.S. § 1332 (a) because this action involves parties who are citizens of different states and the value of the matter in controversy exceeds $ 75,000, exclusive of interests and costs.

42. Venue is proper under 28 U.S.C. § 1391 (a) because this action involves parties who are citizens of different states and the acts or omissions giving rise to the Plaintiff's claim occurred in this Judicial District.

43. Venue is also proper under 28 U.S.C. § 1391 (b) because the Court's jurisdiction is not founded primarily on diversity of citizenship and a substantial part of the events or omissions giving rise to the Plaintiff's claim occurred in this Judicial District.

44. Venue is also proper under 28 U.S.C. § 1391 (c) because the Defendant is a corporation that was subject to the personal jurisdiction of this Court at the time this action commenced, and because the Defendant has contacts sufficient to subject it to the Court's personal jurisdiction if this Court's District were a separate State.

CLASS ACTION ALLEGATIONS

45. Plaintiff brings this action on behalf of herself and all others similarly situated, as members of a proposed Plaintiff class (the "Class") of all individuals who have been implanted with the leads at issue, and propose a Nationwide Class, or in the alternative fifty-one statewide classes, each composed of:

- All residents and domiciliaries of the United States who have been implanted with Sprint Fidelis leads manufactured by Medtronic ("patient recipients"), during the period from January 1, 2004 through the present (the "Class period");

- The estates, representatives, and administrators of deceased patient recipients; and,
- The spouses, children, relatives, and "significant others" of deceased patient recipients as their heirs or survivors.
- Excluded from the proposed subclass are (i) Medtronic, any entity in which Medtronic has a controlling interest or which have a controlling interest in Medtronic, and Medtronic's legal representatives, predecessors, successors and assigns; (ii) the judicial officers to whom this case is assigned; and (iii) any member of the immediate families of excluded persons.

46. The Class is so numerous that the individual joinder of all its members is impracticable. While the exact number and identification of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery of Medtronic, Plaintiff is informed and believes that the Class includes more than 100,000 patient recipients worldwide.

47. This action is brought and may properly be maintained as a class action pursuant to the provisions of *Federal Rule of Civil Procedure* 23(a)(1)-(4), 23(b)(2), and 23(b)(3) and/or 23(c)(4)(A). This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions. Common questions of fact and law exist as to all Class members which predominate over any questions affecting only individual Class members. These common legal and factual questions, which do not vary from Class member to Class member, and which may be determined without reference to the individual circumstances of any Class member, include, but are not limited to, the following:

(a) Whether there are design and/or manufacturing defects in Medtronic's Sprint Fidelis leads;

(b) Whether Medtronic failed to follow United States Food & Drug Administration ("FDA") good manufacturing practices, failed to properly investigate manifestations of the lead defects over the past several years, failed to adequately document reports of the defects, and failed to exercise adequate quality control;

(c) Whether Medtronic's conduct in designing, manufacturing, marketing, and monitoring the Sprint Fidelis leads fell below the duty of care owed by Medtronic to Plaintiff and the other Class members;

(d) Whether Medtronic intentionally, deliberately, uniformly, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed and suppressed material and important information regarding the existence of a defect in the Sprint Fidelis leads from Plaintiff, the FDA, physicians and Class members;

(e) Whether the Sprint Fidelis leads listed in the proposed class definition share common and inherent design and manufacturing defects that cause them to fracture and malfunction, causing inappropriate shocks and failure to deliver an effective shock when needed, creating a risk of injury or death to patients in whom they were implanted;

(f) Whether Medtronic negligently, intentionally, deliberately, uniformly, or recklessly materially misrepresented, concealed, omitted, or suppressed the quality and usefulness of the leads, thereby inducing Plaintiff and the Class to accept implantation of the Sprint Fidelis leads rather than another brand of leads, which would not have been prone to the defects;

(g) Whether Medtronic is liable for selling a dangerously defective product;

(h) Whether Medtronic failed to adequately warn or notify patient recipients, the medical community, and the regulators of the defect, dangers, disadvantages and hazards of the leads;

(i) Whether Medtronic failed to adequately warn or notify hospitals and physicians regarding the defect, malfunction and/or hazards of the defective leads;

(j) Whether Medtronic breached express or implied warranties;

(k) Whether Medtronic's conduct constitutes negligence;

(l) Whether Medtronic is liable for infliction of emotional distress;

(m) Whether Medtronic's misconduct violated applicable consumer protection statutes;

(n) Whether Plaintiff and Class members are entitled to injunctive and other equitable relief, including restitution and disgorgement, and if so, the nature of such relief;

(o) Whether Plaintiff and Class members are entitled to medical monitoring and surveillance and medical treatment at Medtronic's expense;

(p) Whether Medtronic is liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish them for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages;

(q) Whether Medtronic unjustly enriched itself at the expense of Plaintiff and Class members; and,

(r) Which mechanism, among the methods available under the *Federal Rules of Civil Procedure*, is superior to ensure the fair and efficient adjudication of this controversy within the meaning of *Fed. R. Civ. P.* 23(b)(3).

48. Plaintiff's claims are typical of the claims of the Class members. Plaintiff and other Class members must prove the same facts in order to establish the same claims, described herein, which apply to all Class members.

49. Plaintiff is an adequate representative of the Class because she is a member of the Class and her interests do not conflict with the interests of the Class members she seeks to represent. Plaintiff has retained counsel competent and experienced in the prosecution of products liability, mass torts, and consumer fraud class actions, and together Plaintiff and counsel intend to prosecute this action vigorously for the benefit of the Class. The interests of Class members will fairly and adequately be protected by Plaintiff and her counsel.

50. A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual litigation of the claims of all Class members is impracticable. Even if every Class member could afford individual litigation, the court system could not. It would be unduly burdensome to the courts, in which individual litigation of thousands of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, the prospect of a race for the courthouse, and an inequitable allocation

of recovery among those with equally meritorious claims. Individual litigation increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all Medtronic Sprint Fidelis lead claims. By contrast, the class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

51. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of *Federal Rules of Civil Procedure* 23(b)(1) and/or 23(b)(2) because:

(i) The prosecution of separate actions by thousands of individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Medtronic;

(ii) The prosecution of separate actions by individual Class members would also create the risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of the other Class members who are not a party to such adjudications and would substantially impair or impede the ability of such non-party Class members to protect their interests;

(iii) Medtronic has acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and injunctive relief with respect to the Class as a whole.

ALLEGATIONS

52. Medtronic designed, manufactured, marketed, promoted, sold, and distributed 4 models of defective leads, including the Sprint Fidelis 6949 LFJ extendable/retractable screw fixation (S) model; the 6948 LFH tuned fixation (T) model; the 6931 LFT S fixation; and the 6930 LFK fixation (T) model. All of the aforementioned models contain the same defect.

53. The Sprint Fidelis leads were originally approved for sale by the FDA in September 2004.

54. The Sprint Fidelis leads are uniformly defective in that they are prone to fracture of the pace-sense conductor and coil and the HV conductor, causing them to fail to function in a manner which may not be immediately detectable by the patient. The malfunctioning can lead to terrifying inappropriate defibrillation shocks, failure to deliver appropriate (life-giving) defibrillation therapy and death.

55. There is no test that predicts whether the Sprint Fidelis leads will fail.

56. To this day, Medtronic has refused to suggest replacement of the defective Sprint Fidelis leads in its patients, even though in patients whom these defects have been discovered, emergency replacement of the leads is required.

57. Medtronic's failure to document or follow up on the known defects in its Sprint Fidelis leads, and concealment of known defects from the FDA, Plaintiff, the medical community and Class members constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

58. No member of the Class could have discovered the existence of the defect in the Sprint Fidelis leads until, at least, March 2007, when the first physician advisory was sent by Medtronic to physicians concerning the fragile nature of these leads.

59. Medtronic is estopped from relying on the statute of limitations defense because Medtronic actively concealed the lead defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians or class members. Instead of revealing the defects, Medtronic continued to represent its products as safe for their intended use.

60. Medtronic's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Medtronic must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff and Class members.

61. Thousands of patients' lives rely upon the proper functioning of these Sprint Fidelis leads, and they— along with their physicians— have been vigorously attempting to assess the risks that they now face.

62. Patients and physicians remain uninformed and confused about whether the devices should be explanted, or even whether all of the defects have been disclosed.

63. Because of incomplete, inconsistent, and/or confusing information published by Medtronic, it remains unclear how many patients are affected by these defective leads, although based on the population of Medtronic patients whose claims are asserted in this complaints, it is likely to be at least 1,500 and could be as high as 6,000 heart patients in the United States.

64. At all times herein mentioned, Defendant was engaged in the business of, or was successor in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by Plaintiff and the members of her Class. As such, Defendant is individually liable to Plaintiff and her Class for their damages.

65. At all times herein mentioned, the officers and/or directors of the Defendant named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff and the members of her Class.

PLAINTIFF

66. Plaintiff Jeneane Baque has a cardiovascular condition that necessitates the use of an implantable cardiac pacemaker/defibrillator. Ms. Baque was implanted with a cardiac pacemaker/defibrillator combination (an "ICD"). The ICD was attached to her heart with a lead wire system called a Sprint Fidelis lead, model number 6949, manufactured by Medtronic. The Sprint Fidelis lead system was implanted on or about October 19, 2004. After that date, Ms. Baque experienced a number of frightening episodes of unnecessary shocks.

67. Ms. Baque's Sprint Fidelis lead was explanted on March 8, 2007 because it was defective. The lead system itself had fractured. The fracture forced Ms. Baque to have an early

explant of the old lead system and implant of a new one, scarring her already fragile heart, and subjecting her to a variety of other severe emotional and physical harms.

68. The second implanted set of leads were of the same defective variety as the first, bearing the same product number of 6949. This second set of defective leads remain inside her body to this day. Consequently, she continues to be at risk of unnecessary and dangerous electric shocks, in addition to being shadowed by a cloud of dread regarding future spontaneous and unpredictable electric shocks, injuries resulting from those shocks, and possibly death.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Products Liability)

69. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

70. At all relevant times hereto, Medtronic was engaged in the business of designing, manufacturing, assembling, promoting, advertising, selling, and distributing the Sprint Fidelis leads for ultimate sale to, and implantation in, heart disease/disorder patients. Medtronic designed, manufactured, assembled, and sold the Sprint Fidelis leads to hospitals and physicians, knowing that they would be thereby sold to patients with heart diseases and disorders (including Plaintiff and Class members).

71. Medtronic's Sprint Fidelis leads were expected to and did reach Plaintiff and the Class without substantial change in their condition as manufactured and sold by Medtronic. In light of the defects described herein, at the time the leads reached Plaintiff and the Class, they were in a condition not contemplated by any reasonable person among the expected users of the devices, and were unreasonably dangerous to the expected users of the devices when used in reasonably expectable ways of handling or consumption.

72. The Sprint Fidelis leads designed, manufactured, assembled, and sold by Medtronic to Plaintiff and Class members were in a defective condition unreasonably dangerous to any user or consumer of the devices, and Plaintiff and Class members were, and are, in the

class of persons that Medtronic should reasonably have foreseen as being subject to the harm caused by the devices' defective condition.

73. Plaintiff and Class members used the leads in the manner in which the leads were intended to be used. This has resulted in injuries to Plaintiff and Class members.

74. Neither Plaintiff nor Class members, were aware of, and could not in the exercise of reasonable care have discovered, the defective nature of Medtronic's Sprint Fidelis leads, nor could they have known that Medtronic designed, manufactured or assembled the leads in a manner that would increase the risk of bodily injury to them.

75. As a direct and proximate result of Medtronic's design, manufacture, assembly, marketing and sales of the Sprint Fidelis leads, Plaintiff and the Class members have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, and economic losses and consequential damages, and are therefore entitled to compensatory relief, according to proof, and to a declaratory judgment that Medtronic is liable for breach of its duty to them and for its failure to provide a safe and effective medical device. Plaintiff and the Class members are also entitled to equitable relief, as described below.

76. Medtronic's Sprint Fidelis leads constitute a product dangerous for its reasonably intended use, due to defective design, manufacture, assembly, and marketing. Medtronic is therefore liable to Plaintiff and Class members in an amount according to proof.

SECOND CLAIM FOR RELIEF

(Breach of Implied Warranty)

77. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

78. Medtronic impliedly warranted that its Sprint Fidelis leads, which Medtronic designed, manufactured, assembled, promoted and sold to Plaintiff and Class members, were merchantable and fit and safe for ordinary use. Medtronic further impliedly warranted that its Sprint Fidelis leads were fit for the particular purpose of providing prophylactic treatment of patients with a variety of medical issues, including prior myocardial infarction and a limited

ejection fraction, spontaneous and/or inducible life-threatening ventricular arrhythmias, and a high risk for developing such arrhythmias.

79. Medtronic further impliedly warranted that its Sprint Fidelis leads were based on "proven" lead technology and that the Sprint Fidelis leads were easier to implant.

80. Medtronic's Sprint Fidelis leads were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiff and Class members to severe and permanent injuries and death. Therefore, Medtronic breached the implied warranties of merchantability and fitness for a particular purpose when its leads were sold to Plaintiff and Class members, in that the leads are defective and have fractured and otherwise failed to function as represented and intended.

81. As a direct and proximate result of Medtronic's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff and Class members have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, and economic losses, and are therefore entitled to compensatory damages and equitable relief according to proof.

THIRD CLAIM FOR RELIEF

(Negligence)

82. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

83. Medtronic had a duty to Plaintiff and Class members to provide a safe product in design and manufacture, to notify the FDA of design flaws, and to warn the FDA, Plaintiff, and Class members of the defective nature of the Sprint Fidelis leads. Medtronic breached its duty of reasonable care to Plaintiff and Class members by incorporating a defect into the design of the Sprint Fidelis leads, thereby causing Plaintiff's and Class members' injuries.

84. Medtronic breached its duty of reasonable care to Plaintiff and Class members by manufacturing and assembling the Sprint Fidelis leads in such a manner that they were prone to fracture and fail to operate and malfunction and expose Plaintiff and Class members to life-threatening physical trauma.

85. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to notify the FDA at the earliest possible date of known design defects in the leads.

86. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to exercise due care under the circumstances.

87. As a direct and proximate result of the carelessness and negligence of Medtronic as set forth in the preceding paragraphs, Plaintiff and Class members have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages, are entitled to compensatory damages and equitable and declaratory relief according to proof. Medtronic's egregious misconduct alleged above also warrants the imposition of punitive damages against Medtronic.

FOURTH CLAIM FOR RELIEF

(Intentional Infliction of Emotional Distress)

88. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

89. Medtronic engaged in extreme and outrageous conduct, knowingly and/or recklessly marketing defective leads, knowingly and/or recklessly concealing a known and potentially fatal defect from Plaintiff and Class members, and knowingly and/or recklessly misrepresenting the quality and usefulness of the Sprint Fidelis leads.

90. As a direct result of Medtronic's misconduct, Plaintiff and Class members have sustained and will continue to sustain physical injuries and/or death, economic losses, and other damages.

91. Medtronic intended to cause Plaintiff's and Class members' severe emotional distress, or acted with reckless disregard for the Plaintiff's and the Class members' emotional states.

92. Plaintiff and Class members did, in fact, incur (and continue to incur) severe emotional distress as a result of Medtronic's misconduct. Accordingly, Plaintiff and the Class members are entitled to compensatory damages and equitable and declaratory relief according to proof.

93. Medtronic's misconduct alleged above warrants the imposition of punitive damages against Medtronic.

FIFTH CLAIM FOR RELIEF

(Negligent Infliction of Emotional Distress)

94. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

95. Medtronic carelessly and negligently manufactured, marketed and sold defective Sprint Fidelis leads to Plaintiff and Class members, carelessly and negligently concealed these defects from Plaintiff and Class members, and carelessly and negligently misrepresented the quality, safety and usefulness of the leads.

96. Plaintiff and Class members were directly involved in and directly impacted by Medtronic's carelessness and negligence, in that Plaintiff and Class members have sustained and will continue to sustain severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase, use and have implanted in their bodies a defective and dangerous product manufactured, sold and distributed by Medtronic.

97. Medtronic's misconduct as alleged above has caused Plaintiff and Class members to suffer severe emotional trauma, physical consequences and long continued emotional disturbance. Plaintiff and Class members are therefore entitled to compensatory damages and equitable and declaratory relief according to proof.

SIXTH CLAIM FOR RELIEF

(Violation of Consumer Protection Statutes)

98. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

99. Defendant has a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the defective leads.

100. Had the Defendant not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the defective leads, and would not have incurred related medical costs.

101. Defendant's deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and practices in violation of the state consumer protection statutes listed below.

102. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the defective leads that they would not have paid had Defendant not engaged in unfair and deceptive conduct.

103. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes, as listed below:

(a) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, et seq.;

(b) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, et seq.;

(c) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, et seq.;

(d) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, et seq.;

(e) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §1770, et seq. and Cal. Bus. & Prof. Code § 17200, et seq.;

(f) Defendant has engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, et seq.;

(g) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110a, et seq.;

(h) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code §§ 2511, et seq. and 2531, et seq.;

(i) Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, et seq.;

(j) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.;

(k) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §§10-1-372, et seq., 10-1-392 and 10-1-420.

(l) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480-1, et seq.;

(m) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, et seq.;

(n) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, et seq.;

(o) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5-1, et seq.;

(p) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.16, et seq.;

(q) Defendant ha engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.;

(r) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.170, et seq.;

(s) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.;

(t) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 205A, et seq.;

(u) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, et seq.;

(v) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.;

(w) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann. § 445.901, et seq.;

(x) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §§ 325D.43, et seq., 325F.67, et seq. and 325F.68 et seq.;

(y) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, et seq.;

(z) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Ann. Missouri Stat. § 407.010, et seq.;

(aa) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Ann. § 30-14-101, et seq.;

(bb) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, et seq.;

(cc) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. § 598.0903, et seq.;

(dd) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, et seq.;

(ee) Defendant has engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, et seq.;

(ff) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, et seq.;

(gg) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§ 349 et seq. and 350-e, et seq.;

(hh) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.;

(ii) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. CODE §§ 51-12-01, et seq., and 51-15-01, et seq.;

(jj) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.;

(kk) Defendant has engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, et seq.;

(ll) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.;

(mm) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, et seq.;

(nn) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, et seq.;

(oo) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, et seq.;

(pp) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws § 37-24-1, et seq.;

(qq) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, et seq.;

(rr) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.;

(ss) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, et seq.;

(tt) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, et seq.;

(uu) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.;

(vv) Defendant has engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, et seq.;

(ww) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, et seq.;

(xx) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, et seq.; and

(yy) Defendant has engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-101, et seq.

104. Plaintiff and her Class were injured by the cumulative and indivisible nature of Defendant's conduct. The cumulative effect of Defendant's conduct directed at patients, physicians and consumers was to create demand for and sell the defective leads. Each aspect of Defendant's conduct combined to artificially create sales of the defective leads.

105. The medical community relied upon Defendant's misrepresentations and omissions in determining which cardiac device to utilize.

106. By reason of the unlawful acts engaged in by Defendant, Plaintiff and her Class have suffered ascertainable loss and damages.

107. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff and her Class were damaged by paying in whole or in part for these defective leads.

108. As a direct and proximate result of Defendant's violations of state consumer protection statutes, Plaintiff and her Class have sustained economic losses and other damages for which they are entitled to statutory, compensatory damages and declaratory relief in an amount to be proven at trial. Defendant is liable to Plaintiff and each member of her Class jointly and severally for all general, special and injunctive relief to which Plaintiff and her Class are entitled by law. Under statutes enacted in California and all other states, and the District of Columbia, to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Plaintiff and Class members are consumers who purchased Medtronics' Sprint Fidelis leads pursuant to a consumer transaction for personal use and are therefore subject to protection under such legislation.

109. Under statutes enacted in California and all other states, and the District of Columbia, to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Medtronic is the supplier, manufacturer, advertiser, and seller, who is subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

110. Defendant violated the statutes enacted in California and all other states, and the District of Columbia, to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the leads were fit to be used for the purpose for which they were intended, when in fact the leads were defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials.

111. The actions and omissions of Defendant alleged herein are uncured or incurable deceptive acts under the statutes enacted in California and all other states, and the District of Columbia, to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

112. Defendant had actual knowledge of the defective and dangerous condition of the Sprint Fidelis leads, and failed to take any action to cure such defective and dangerous conditions.

SEVENTH CLAIM FOR RELIEF

(Breach of Express Warranties)

113. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

114. Defendant expressly warranted to Plaintiff by and through Defendant and/or its authorized agents or sales representatives, in publications, the internet, and other communications intended for medical patients, and the general public, that the defective leads were safe, effective, fit and proper for their intended use.

115. In allowing the implantation of the defective leads, Plaintiffs relied on the skill, judgment, representations, and express warranties of Defendant. These warranties and

representations were false in that the defective leads were not safe and were unfit for the uses for which they were intended.

116. Through its sale of the defective leads, Defendant is a merchant pursuant to Section 2-314 of the *Uniform Commercial Code*.

117. Any disclaimers of express warranties are ineffectual as they were not provided to Plaintiff and her Class or otherwise made known to them. In addition, any such disclaimers are unconscionable.

118. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have sustained economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and damages to Plaintiff and her Class in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential damages in unconscionable. Defendant is liable to Plaintiff each member of her Class jointly and severally for all damages to which Plaintiff and her Class are entitled by law.

EIGHTH CLAIM FOR RELIEF

(Unjust Enrichment)

119. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

120. As the intended and expected result of their conscious wrongdoing, Defendant has profited and benefited from the purchase of Defendant's defective leads by Plaintiff and each member of her Class.

121. Defendant has voluntarily accepted and retained these profits and benefits, derived from the Plaintiff and Plaintiff's Class, with full knowledge and awareness that, as a result of Defendant's wrongdoing, Plaintiff and her Class were not receiving a product of the quality, nature or fitness that had been represented by Defendant or that Plaintiff and the members of her Class, as reasonable consumers, expected.

122. By virtue of the conscious wrongdoing alleged above, Defendant has been unjustly enriched at the expense of the Plaintiff and her Class, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendant's wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendant's unjust enrichment.

NINTH CLAIM FOR RELIEF

(Declaratory Relief and Medical Monitoring)

123. Plaintiff, on behalf of herself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

124. Plaintiff and Class members have no adequate remedy at law and damages cannot adequately compensate Plaintiff and Class members for the injuries suffered and threatened, rendering declaratory, injunctive, and other equitable relief appropriate.

125. Through the unlawful conduct set forth in the preceding paragraphs, Plaintiff and tens of thousands of Class members have been implanted with a device which tends to fracture, and otherwise malfunction. These defects have potentially fatal consequences for many patients who rely upon the presence of the leads connected to the ICDs to regulate their cardiac rhythms.

126. There are medical risks to Plaintiff and Class members associated with having the defective Sprint Fidelis leads explanted, as they have been implanted directly onto the heart wall. Explantation procedures expose Plaintiff and Class members to significant risks attendant to surgery, not least of which are potentially life-threatening infections and other harm.

127. At the same time, Plaintiff and Class members, along with their physicians, must weigh these risks against the possibility that Medtronic's Sprint Fidelis leads will fail or have failed to function as designed, represented and intended, resulting in an increased risk of heart damage, failure and/or death.

128. Accordingly, Plaintiff, on behalf of herself and all others similarly situated, request the following classwide equitable relief:

(a) That Medtronic be ordered to notify all potential Class members of the defective nature of the Sprint Fidelis leads;

(b) That Medtronic be ordered to create a treatment fund, under the continuing jurisdiction and supervision of this Court, to monitor the health of Plaintiff and Class members, and to pay or reimburse Plaintiff and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses caused by Medtronic's wrongdoing; and

(c) Declaratory judgment that Medtronic is liable to Plaintiff and all Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of herself and all others similarly situated, prays for judgment against Medtronic as follows:

1. For an Order certifying the Class and any appropriate subclasses thereof under the appropriate provisions of Federal Rule of Civil Procedure 23, and appointing Plaintiff and her counsel to represent the Class;

2. For the equitable relief requested;

3. For compensatory damages according to proof;

4. For punitive or exemplary damages against Medtronic, consistent with the degree of Medtronic's reprehensibility and the resulting harm or potential harm to Plaintiff and the Class, and in an amount sufficient to punish Medtronic and deter others from similar wrongdoing;

5. For all applicable statutory damages under the consumer protection legislation of California, and all states and the District of Columbia;

6. For declaratory judgment that Medtronic is liable to Plaintiff and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing;

7. For notice to be disseminated to all Class members who have been implanted with Sprint Fidelis leads;

8. For a restitution and disgorgement of profits;

9. For an award of attorneys' fees and costs;

10. For prejudgment interest and the costs of suit; and

11. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of herself and all others similarly situated, hereby demands a trial by jury in this case as to such issues so triable.

Dated: 19 October 2007

EDGAR LAW FIRM

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

WILLIE WEST and PAMELA WEST on behalf of themselves and all Others Similarly Situated,

Plaintiffs,

v.

MEDTRONIC, INC., MEDTRONIC PUERTO RICO, INC., and MEDTRONIC PUERTO RICO OPERATIONS CO.,

Defendants.

CASE NO. _____

CLASS ACTION COMPLAINT

DEMAND FOR JURY TRIAL

Plaintiffs Willie West and Pamela West ("Plaintiffs" or "Plaintiff West"), by their undersigned counsel, for themselves and all others similarly situated, hereby commence this class action against Medtronic, Inc., Medtronic Puerto Rico, Inc., and Medtronic Puerto Rico Operations Co. (hereinafter collectively "Defendants" or "Medtronic" or the "Company," unless otherwise stated) for compensatory, equitable, injunctive, and declaratory relief. Plaintiffs make

the following allegations based upon their personal knowledge as to their own acts, and upon information and belief, as well as upon their attorneys' investigative efforts as to Medtronic's actions and misconduct, and alleges as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 and the Class Action Fairness Act of 2005. The matter in controversy in this class action exceeds $5,000,000, exclusive of interest and costs, and some members of the class are citizens of states other than the states in which Defendants are incorporated and have their principal place of business.

2. Venue is also proper under 28 U.S.C. § 1391(a) because this action involves parties who are citizens of different states and the acts or omissions giving rise to the Plaintiffs' claim occurred in this Judicial District.

3. Venue is also proper under 28 U.S.C. § 1391(b) because the Court's jurisdiction is not founded primarily on diversity of citizenship and a substantial part of the events or omissions giving rise to the Plaintiffs' claim occurred in this Judicial District.

4. Venue is also proper under 28 U.S.C. § 1391 because Defendant Medtronic, Inc. conducts business in this District and all three defendants earn substantial compensation and profits from sales of Sprint Fidelis leads in this District.

INTRADISTRICT ASSIGNMENT

5. Pursuant to Civil L.R. 3-5(b) and Civil L.R. 3-2(d), Plaintiffs state that assignment of this action to the San Francisco Division of this Court is appropriate because the acts or omissions giving rise to the Plaintiffs' claim occurred in this Judicial District and Defendant Medtronic, Inc. conducts in this District and all three defendants earn substantial compensation and profits from sales of Sprint Fidelis leads in this District.

INTRODUCTION

6. This is a nationwide class action brought on behalf of Plaintiffs and other individuals similarly situated who, during the period of January 1, 2004 through October 15, 2007, were implanted with the defective Sprint Fidelis leads (the "leads") that were designed,

manufactured, promoted, marketed, distributed and sold by Medtronic under the following model numbers:

(a) the 6949 LFJ extendable/retractable screw fixation (S) model;

(b) the 6948 LFH tuned fixation (T) model;

(c) the 6931 LFT S fixation; and

(d) the 6930 LFK T fixation.

7. These leads were first approved by the FDA in September of 2004 and since that time have been implanted in approximately 268,000 patients worldwide, including 144,000 implanted in patients in the United States. On March 21, 2007, Medtronic issued a physician advisory warning doctors that the Company was investigating reports of lead failures. Thereafter, on October 15, 2007, Medtronic recalled all un-implanted leads, stating that there was a reasonable probability that the leads could cause serious injury or death. The Company further recommended that all implanted leads be monitored.

8. At all relevant times, Medtronic misrepresented the safety of the Sprint Fidelis leads, and negligently manufactured, marketed, advertised, promoted, sold and distributed the leads as safe and effective devices to be used for implantation with implantable cardiac devices ("ICDs") for prophylactic treatment of patients with prior myocardial infarction and a limited ejection fraction, patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias.

9. As a result of their defective design and manufacture, the Sprint Fidelis leads can fail and cause serious physical trauma and/or death. Medtronic knew and had reason to know of this tendency and the resulting risk of injuries and deaths, but concealed this information and did not warn Plaintiff or her physicians, preventing Plaintiff, the Class and their physicians, and the medical community from making informed choices about the selection of leads for implantation. Approximately 129,000 of the affected devices remain in service in the United States.

10. As a result of the defective and hazardous leads, Plaintiff and other members of the Class have incurred injuries and damages. Plaintiff and other members of the Class seek injunctive, compensatory, equitable, statutory and punitive relief. In addition, Plaintiff and the

class seek declaratory relief and a medical monitoring program for class members who are implanted with the defective leads.

PARTIES

11. Individual and representative Plaintiff Willie West is a citizen and resident of the County of Alameda, State of California,. Plaintiff West has a cardiovascular condition that necessitates the use of an ICD. Plaintiff West was implanted with an ICD and leads on October 1, 2004 at Washington Hospital in Fremont, California. The ICD was attached to his heart with a lead wire system called a Sprint Fidelis lead, model number 6949, manufactured by defendants, and each of them.

12. Plaintiff Pamela West is a citizen and resident of the County of Alameda, State of California. She is the spouse of Willie West, and claims damages as set forth below.

13. Defendant Medtronic, Inc. is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Medtronic develops technology to treat conditions such as heart disease and other illnesses. Medtronic manufactures medical devices and sells them worldwide. Medtronic's Cardiac Rhythm Disease Management Division ("CRM Division") is the division that develops, researches, advertises, promotes, markets and sells all of Medtronic ICDs, and leads, some of which are marketed under the trade name "Sprint Fidelis." CRM Division's operations are principally conducted out of its facilities at Cardiac Rhythm Disease Management at 7000 Central Ave., Minneapolis, Minnesota 55432.

14. Defendant Medtronic Puerto Rico, Inc. is a corporation existing by virtue of the laws of the Territory of Puerto Rico, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

15. Defendant Medtronic Puerto Rico Operations Co., Inc. is a corporation existing by virtue of the laws of the Territory of Puerto Rico, with its principal place of business at Road 149, km 56.3, Box 6001 Villalba, PR.

16. Medtronic Puerto Rico, Inc. and Medtronic Puerto Rico Operations Co., Inc. are the wholly owned subsidiaries of Medtronic, Inc. and formulate, develop, manufacture and sterilize the devices at issue in this lawsuit.

SUBSTANTIVE ALLEGATIONS

A. Use of Implantable Cardiac Devices

17. Medtronic designs, researches, develops, manufactures, tests, markets, advertises, promotes, distributes, and sells products that treat cardiac arrhythmias, heart failure, and coronary and peripheral vascular disease. An arrhythmia is an irregular cardiac rhythm, which can cause significantly decreased cardiac output and ultimately, death. Medtronic considers itself to be "the global leader in medical technology, alleviating pain, restoring health, and extending life for millions of people around the world." See Medtronic's annual report for the year ended April 27, 2007, filed on Form 10-K on June 25, 2007, available at http://www.sec.gov/Archives/edgar/data/64670/000089710107001326/0000897101-07-001326-index.htm, last visited on November 6, 2007.

18. Medtronic and other manufacturers produce a number of devices designed to detect and treat abnormally fast and irregular heart rhythms and to provide pacing for improper heart rhythms, including ICDs. ICDs contain pacemakers as well as defibrillators. While a pacemaker is used primarily to correct slow heart rates, an ICD detects and corrects both fast and slow heart rates. The pacemaker portion corrects the slow rates and the anti-tachycardia portion can "over-drive pace" rapid rates. The defibrillator portion can shock ventricular tachycardia and ventricular fibrillation to stop the heart and allow an appropriate rhythm to take over.

19. ICDs are designed to be implanted primarily under the skin of the chest wall. The device's power source, or pulse generator, is implanted in a pouch formed in the chest wall generally over the left pectoralis major muscle.

20. Wires called "leads" are typically inserted through a major vein and attached directly to the muscle on the inside of the heart. Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart, where they monitor the heartbeat and can administer an electric shock to abort a dangerous "over-drive pace," a very rapid rhythm, or pace the heart at a normal rhythm if an irregularity is detected.

21. Such devices are used in patients, like Plaintiff, who have arrhythmias or irregular heartbeats that are considered life-threatening. The Class members with these medical problems

include patients who are at risk for conditions such as ventricular fibrillation (rapid, ineffective contraction of the ventricles of the heart) or ventricular tachycardia (excessively rapid heartbeat), which are poorly controlled by medication. Without the therapy provided by an appropriate device to put the heart back into an appropriate cardiac rhythm, these arrhythmias or irregular heart beats can result in the loss of consciousness or death.

22. If an implanted ICD and lead operate properly, the system can save a patient's life. If either the ICD or the leads fail to operate properly, the patient may be seriously injured or die.

23. The majority of ICDs now use two or three leads. As a result, smaller high-voltage leads are attractive to electrophysiologists because they are believed to be easier to insert, and are less likely to obstruct blood flow or distort the tricuspid valve.

B. Medtronic Introduces the Sprint Fidelis Lead

24. In 2001, Medtronic marketed its then-smallest defibrillation lead called the Sprint Quattro Secure, model 6947 ("Quattro leads").

25. On September 2, 2004, Medtronic announced that it had received approval by the United States Food and Drug Administration (the "FDA") for the sale of its Sprint Fidelis leads, which it introduced and marketed as "the world's smallest right ventricular defibrillation leads." See Medtronic Announces U.S. FDA Approval Of New Defibrillation Leads For Patients At Risk Of Sudden Cardiac Arrest, The Nation's No. 1 Killer, September 2, 2004 (hereinafter, "Sept. 2nd Release"), available at http://wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1095281834568&format=print&lang=en_US, last visited on November 6, 2007.

26. These Sprint Fidelis leads were researched, developed, manufactured, marketed, promoted, advertised, sold, and distributed by Medtronic to be used in connection with ICDs.

27. At the time that Medtronic announced the marketing of the Sprint Fidelis leads, Medtronic claimed that "[t]he small size of the Sprint Fidelis (Fidelis is a Latin word that means faithful') helps improve passage into a patient's venous system for an easier implant, and minimizes venous obstruction." Medtronic also touted these leads as "state-of-the-art." See Sept. 2nd Release.

28. Medtronic further represented that the Sprint Fidelis leads were based on the "proven" design of the Quattro leads. Indeed, Medtronic sought to replace the Quattro leads with the Sprint Fidelis leads as the high voltage lead of choice and to attempt to gain a larger market share.

29. The Sprint Fidelis leads are 6.6 French isodiametric multifilar true bipolar high voltage leads with silicone insulation and polyurethane outer coating. French is a measure of circumference used for these leads. The Models 6949 and 6948 have two high voltage coils; the 6930 and 6931 models have a single right ventricular high voltage coil. As of January 2007, approximately 160,000 Sprint Fidelis leads have been implanted in patients worldwide, including 144,311 model 6949 leads, 7,510 model 6948 leads, 5,387 model 6931 leads, and 236 model 6930 leads.

C. The Defective Sprint Fidelis Leads

30. Since the introduction of the leads to the market, it has become apparent that a significant portion of the leads have potentially serious and/or fatal defects. These defects were discussed in an article written by doctors at The Minneapolis Heart Institute, one of the premiere heart institutes in the world, based on a study of the incidence of lead failures in the Sprint Fidelis models compared to the Sprint Quattro models. According to the report, which was prepared by Dr. Robert G. Hauser, et al., and published in the Heart Rhythm Society Journal in the Spring of 2007, "Early Failure of Small-Diameter High-Voltage Inflammable Cardioverter-Defibrillator Lead," Heart Rhythm Society 2007.03.041 (2007) (hereinafter, "Early Failures"), the Minneapolis Heart Institute's experience reflected that, between September 2004 and February 2007, 583 patients were implanted with Sprint Fidelis Model 6949 leads, and nine patients received other Sprint Fidelis models. During that time, six patients experienced Sprint Fidelis Model 6949 lead failures. The failed Sprint Fidelis Model 6949 leads had been implanted by various electrophysiologists, cardiologists and thoracic surgeons. The average time to failure was fourteen months (based on a range of four to twenty-three months). Early Failures, p. 893.

31. The study compared the actuarial survival of the 583 Sprint Fidelis Model 6949 leads implanted at the Minneapolis Heart Institute to the survival of 285 Sprint Quattro Model

6947 leads implanted at the Institute between November 2001 and March 2007. The difference in survival between the Sprint Fidelis Model 6949 lead and the Sprint Quattro Secure Model 6947 lead was extremely significant. The failure rate for the Sprint Fidelis Model 6949 lead was 1-2% during the first two years of implant and was ten times greater than the failure rate for the Sprint Quattro Secure Model 6947 lead. Early Failures, p. 893-894.

32. The significant number of lead failures involved lead fractures of the PACE-sense conductor or coil in the Sprint Fidelis Model 6949. The fracture rate for the Sprint Fidelis leads was three times higher than the fracture rate of the Quattro Model 6947. Early Failures, p. 894-895.

33. Another study, conducted at Cornell University Medical Center by Sunil Mirchandani, et al., found that a "17% incidence of abnormal [right ventricular] sensing was observed during follow-up of [patients] implanted with the Medtronic Sprint Fidelis ICD lead" which "necessitated an early revision of the system in 4% of [patients]." See Abstract of Defibrillator Leads: Is Smaller Necessarily Better?, 2006, available at http://vivo.library.cornell.edu/entity?home=&id=30168, last visited on November 6, 2007.

34. Medtronic has not disclosed the precise mechanism of the Sprint Fidelis lead fracture failures. However, it appears that the defect in the Sprint Fidelis may be attributable to the smaller diameter of the coil and conductors. As a result of this small diameter, the leads are subject to stress damage both during and after implantation, and fracture eventually occurs when the conductor is critically overstressed. The number of fractures that have been observed in these leads indicates that there is a clear defect in the leads themselves, and that defect was demonstrated in the 6931 leads that were implanted in Plaintiff West.

35. In addition, a review of the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database, which contains reports of adverse events associated with the use of medical devices, reveals that, as of July 2007, over 1000 Medical Device Reports ("MDR's") regarding Sprint Fidelis lead had been filed since September 2004. The most frequent complaints were fracture and inappropriate shocks, and the most common observations were high impedance, oversensing and noise, and failure to capture or high threshold.

36. Medtronic analyzed approximately 125 of those leads that were returned to Medtronic before July 2006. According to the relevant MDR reports, Medtronic concluded that 77 out of 125 leads (or 62%) were defective. The predominant manifestation of the defect was conductor fracture, involving the PACE-sense conductor and coil or the high voltage (defibrillation) conductor. PACE-sense conductor or coil fracture was manifested by inappropriate shocks or oversensing/noise and high impedance, while high voltage conductor fracture was primarily linked to high impedance.

37. In addition, Medtronic itself filed more than 350 additional MDRs regarding the Sprint Fidelis leads between August 2006 and February 2007. However, Medtronic did not include similar analysis of those leads in the MDRs it filed during this period.

38. On March 21, 2007, Medtronic issued a physician advisory, in the nature of a "Dear Doctor Letter," that advised physicians of "the higher than expected conductor fracture rates in … Sprint Fidelis leads." In this letter, Medtronic claimed to be investigating reports of lead failures, however, it still represented that the Sprint Fidelis leads were performing consistent with, and "in line with other Medtronic leads …. And consistent with lead performance publicly reported by other manufacturers." This letter also stated, "…variables within the implant procedure may contribute significantly to these fractures… For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area." At no time prior to this letter did Medtronic warn physicians that its leads must be specially handled during the implantation procedure or that they could "severely bend" or "kink" if they are implanted using certain accepted implant techniques.

39. On October 15, 2007, Medtronic issued a Class 1 Recall of all un-implanted Sprint Fidelis leads model numbers 6949 LFJ extendable/retractable screw fixation (S) model; the 6948 LFH tuned fixation (T) model; the 6931 LFT S fixation; and the 6930 LFK fixation (T) model. According to the FDA recall notice, a Class 1 recall is the most serious type of recall and involves situations in which there is a "reasonable probability that use of the product will cause serious injury or death." The recall also urged individuals who have been implanted with Sprint Fidelis

leads to contact their physician. See Class 1 Recall: Medtronic Inc. Sprint Fidelis® Defibrillator Leads, available at http://www.fda.gov/cdrh/recalls/recall-101507.html, last visited on November 6, 2007.

40. During the Class Period, and at all other relevant times, Medtronic misrepresented the safety of the Sprint Fidelis leads and negligently manufactured, marketed, advertised, promoted, sold, and distributed the leads as safe devices to be used together with ICDs for prophylactic treatment of patients with prior myocardial infarction and a decreased ejection fraction, ventricular arrhythmias, and patients who are at high risk for developing such arrhythmias. Some patients are dependent on such devices to maintain an appropriate heart rhythm, and therefore, adequate cardiac output. For these patients, failure of the leads connected to the ICD can cause sudden faintness, or loss of consciousness, and can result in death.

41. As a result of their defective design and manufacture, Medtronic's Sprint Fidelis leads suffer fracture or other failure, leading to malfunction in the transmission of the electric signal from the ICD to the patient's heart, which can cause serious physical trauma and/or death. Medtronic knew and had reason to know of this tendency and the resulting risk of injuries and deaths, but concealed this information and did not warn Plaintiff or her physicians, preventing Plaintiff, the Class and their physicians, and the medical community from making informed choices about the selection of leads for implantation.

42. At all times relevant to this action, Medtronic knew, and had reason to know, that the Sprint Fidelis leads were not safe for the patients for whom they were prescribed and implanted, because the leads fractured and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing serious medical problems and, in some patients, catastrophic injuries and deaths. Indeed, Medtronic's representation of the consistency of the performance of the Sprint Fidelis leads is untrue in light of the reported experience with the leads and the various issues included in the MAUDE database reports.

43. At all times relevant to this action, Medtronic knew, and had reason to know, that its representations that the Sprint Fidelis leads were easier to implant and based on "proven" technology were materially false and misleading.

44. At all relevant times, Medtronic failed to warn that the Sprint Fidelis leads were prone to breakage or that particular processes should be implemented in order to avoid breaking the Sprint Fidelis leads.

45. The Sprint Fidelis leads are uniformly defective in that they are prone to fracture of the PACE-sense conductor and coil and the HV conductor, causing them to fail to function in a manner which may not be immediately detectable by the patient. The malfunctioning can lead to terrifying inappropriate defibrillation shocks, failure to deliver appropriate (life-giving) defibrillation therapy and death.

46. There is no test that predicts which Sprint Fidelis leads will fail.

47. To this day, Medtronic has refused to suggest replacement of the defective Sprint Fidelis leads in its patients, even though in patients whom these defects have been discovered, emergency replacement of the leads is required.

D. Medtronic Concealed the Defects of the Leads

48. Medtronic's failure to document or follow up on the known defects in its Sprint Fidelis leads, and concealment of known defects from the FDA, Plaintiff, the medical community and Class members constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

49. No member of the Class could have discovered the existence of the defect in the Sprint Fidelis leads until, at least, March 2007, when the first physician advisory was sent by Medtronic to physicians concerning the fragile nature of these leads.

50. Medtronic is estopped from relying on the statute of limitations defense because Medtronic actively concealed the lead defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians or class members. Instead of revealing the defects, Medtronic continued to represent its products as safe for their intended use.

51. Medtronic's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Medtronic must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff and Class

members.

E. Medtronic Failed to Provide Adequate and Accurate Information About the Leads

52. Thousands of patients' lives rely upon the proper functioning of these Sprint Fidelis leads, and they — along with their physicians — have been vigorously attempting to assess the risks that they now face.

53. Patients and physicians remain uninformed and confused about whether the devices should be explanted, or even whether all of the defects have been disclosed.

54. Because of incomplete, inconsistent, and/or confusing information published by Medtronic, it remains unclear how many patients are affected by these defective leads, although based on the population of Medtronic patients whose claims are asserted in this complaints, it is likely to be at least 1,500 and could be as high as 6,000 heart patients in the United States.

F. Medtronic's Corporate Liability

55. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to Plaintiff.

56. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

57. At all times herein mentioned, Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling,

inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiff for Plaintiff's damages.

58. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

CLASS ACTION ALLEGATIONS

59. Plaintiffs bring this action on behalf of themselves and all others similarly situated, as members of a proposed plaintiff class (the "Class") of all individuals who have been implanted with the leads at issue, and propose a Nationwide Class, or in the alternative fifty-one statewide classes, each composed of:

(a) All residents and domiciliaries of the United States who have been implanted with Sprint Fidelis leads manufactured by Medtronic ("patient recipients"), during the period from January 1, 2004 through October 15, 2007 (the "Class period");

(b) The spouses of patient recipients;

(c) The estates, representatives, and administrators of deceased patient recipients; and

(d) The spouses, children, relatives, and "significant others" of deceased patient recipients as their heirs or survivors.

(e) Excluded from the proposed subclass are (i) Medtronic, any entity in which Medtronic has a controlling interest or which have a controlling interest in Medtronic, and Medtronic's legal representatives, predecessors, successors and assigns; (ii) the judicial officers to whom this case is assigned; and (iii) any member of the immediate families of excluded persons.

60. The Class is so numerous that the individual joinder of all its members is impracticable. While the exact number and identification of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery of Medtronic,

Plaintiff is informed and believes that the Class includes more than 100,000 patient recipients worldwide.

61. This action is brought and may properly be maintained as a class action pursuant to the provisions of Federal Rule of Civil Procedure 23(a)(1)-(4), 23(b)(2), and 23(b)(3) and/or 23(c)(4)(A). This action satisfies the numerosity, commonality, typicality, adequacy, predominance, and superiority requirements of those provisions. Common questions of fact and law exist as to all Class members which predominate over any questions affecting only individual Class members. These common legal and factual questions, which do not vary from Class member to Class member, and which may be determined without reference to the individual circumstances of any Class member, include, but are not limited to, the following:

(a) Whether there are design and/or manufacturing defects in Medtronic's Sprint Fidelis leads;

(b) Whether Medtronic failed to follow United States Food & Drug Administration ("FDA") good manufacturing practices, failed to properly investigate manifestations of the lead defects over the past several years, failed to adequately document reports of the defects, and failed to exercise adequate quality control;

(c) Whether Medtronic's conduct in designing, manufacturing, marketing, and monitoring the Sprint Fidelis leads fell below the duty of care owed by Medtronic to Plaintiff and the other Class members;

(d) Whether Medtronic intentionally, deliberately, uniformly, knowingly, carelessly, recklessly, or negligently misrepresented, omitted, concealed and suppressed material and important information regarding the existence of a defect in the Sprint Fidelis leads from Plaintiff, the FDA, physicians and Class members;

(e) Whether the Sprint Fidelis leads listed in the proposed class definition share common and inherent design and manufacturing defects that cause them to fracture and malfunction, causing inappropriate shocks and failure to deliver an effective shock when needed, creating a risk of injury or death to patients in whom they were implanted;

(f) Whether Medtronic negligently, intentionally, deliberately, uniformly, or

recklessly materially misrepresented, concealed, omitted, or suppressed the quality and usefulness of the leads, thereby inducing Plaintiff and the Class to accept implantation of the Sprint Fidelis leads rather than another brand of leads, which would not have been prone to the defects;

(g) Whether Medtronic is liable for selling a dangerously defective product;

(h) Whether Medtronic failed to adequately warn or notify patient recipients, the medical community, and the regulators of the defect, dangers, disadvantages and hazards of the leads;

(i) Whether Medtronic failed to adequately warn or notify hospitals and physicians regarding the defect, malfunction and/or hazards of the defective leads;

(j) Whether Medtronic breached express or implied warranties;

(k) Whether Medtronic's conduct constitutes negligence;

(l) Whether Medtronic is liable for infliction of emotional distress;

(m) Whether Medtronic's misconduct violated applicable consumer protection statutes;

(n) Whether Plaintiffs and Class members are entitled to injunctive and other equitable relief, including restitution and disgorgement, and if so, the nature of such relief;

(o) Whether Plaintiffs and Class members are entitled to medical monitoring and surveillance and medical treatment at Medtronic's expense;

(p) Whether Medtronic is liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish them for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages;

(q) Whether Medtronic unjustly enriched itself at the expense of Plaintiff and Class members; and

(r) Which mechanism, among the methods available under the Federal Rules of Civil Procedure, is superior to ensure the fair and efficient adjudication of this controversy within the meaning of Fed. R. Civ. P. 23(b)(3).

62. Plaintiffs' claims are typical of the claims of the Class members. Plaintiffs and other Class members must prove the same facts in order to establish the same claims, described

herein, which apply to all Class members.

63. Plaintiffs are adequate representatives of the Class because they is a member of the Class and their interests do not conflict with the interests of the Class members they seek to represent. Plaintiffs have retained counsel competent and experienced in the prosecution of products liability, mass torts, and consumer fraud class actions, and together Plaintiffs and counsel intend to prosecute this action vigorously for the benefit of the Class. The interests of Class members will fairly and adequately be protected by Plaintiffs and their counsel.

64. A class action is superior to other available methods for the fair and efficient adjudication of this litigation since individual litigation of the claims of all Class members is impracticable. Even if every Class member could afford individual litigation, the court system could not. It would be unduly burdensome to the courts, in which individual litigation of thousands of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, the prospect of a race for the courthouse, and an inequitable allocation of recovery among those with equally meritorious claims. Individual litigation increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all Medtronic Sprint Fidelis lead claims. By contrast, the class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

65. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Federal Rules of Civil Procedure 23(b)(1) and/or 23(b)(2) because:

(a) The prosecution of separate actions by thousands of individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Medtronic;

(b) The prosecution of separate actions by individual Class members would also create the risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of the other Class members who are not a party to such adjudications and would substantially impair or impede the ability of such non-party Class members to protect

their interests;

(c) Medtronic has acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and injunctive relief with respect to the Class as a whole.

CLAIMS FOR RELIEF

COUNT I

Strict Products Liability

66. Plaintiff, on behalf of himself and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

67. At all relevant times hereto, Medtronic was engaged in the business of designing, manufacturing, assembling, promoting, advertising, selling, and distributing the Sprint Fidelis leads for ultimate sale to, and implantation in, heart disease/disorder patients. Medtronic designed, manufactured, assembled, and sold the Sprint Fidelis leads to hospitals and physicians, knowing that they would be thereby sold to patients with heart diseases and disorders (including Plaintiff and Class members).

68. Medtronic's Sprint Fidelis leads were expected to and did reach Plaintiff and the Class without substantial change in their condition as manufactured and sold by Medtronic. In light of the defects described herein, at the time the leads reached Plaintiff and the Class, they were in a condition not contemplated by any reasonable person among the expected users of the devices, and were unreasonably dangerous to the expected users of the devices when used in reasonably expectable ways of handling or consumption.

69. The Sprint Fidelis leads designed, manufactured, assembled, and sold by Medtronic to Plaintiff and Class members were in a defective condition unreasonably dangerous to any user or consumer of the devices, and Plaintiffs and Class members were, and are, in the class of persons that Medtronic should reasonably have foreseen as being subject to the harm caused by the devices' defective condition.

70. Plaintiff Willie West and other Class Members used the leads in the manner in which the leads were intended to be used. This has resulted in injuries to Plaintiff and Class

Members.

71. Neither Plaintiff nor Class members, were aware of, and could not in the exercise of reasonable care have discovered, the defective nature of Medtronic's Sprint Fidelis leads, nor could they have known that Medtronic designed, manufactured or assembled the leads in a manner that would increase the risk of bodily injury to Plaintiff and the Class.

72. As a direct and proximate result of Medtronic's design, manufacture, assembly, marketing and sales of the Sprint Fidelis leads, Plaintiff and the Class members have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, and economic losses and consequential damages, and are therefore entitled to compensatory relief according to proof, and entitled to a declaratory judgment that Medtronic is liable to them for breach of its duty to Plaintiff and the Class members and Medtronic's failure to provide a safe and effective medical device; and Plaintiff and the Class members are entitled to equitable relief as described below.

73. Medtronic's Sprint Fidelis leads constitute a product dangerous for its reasonably intended use, due to defective design, manufacture, assembly, and marketing. Medtronic is therefore liable to Plaintiff and Class members in an amount according to proof.

COUNT II

Breach of Implied Warranty

74. Plaintiffs, on behalf of themselves and all others similarly situated, re-allege the allegations contained in the foregoing paragraphs.

75. Medtronic impliedly warranted that its Sprint Fidelis leads, which Medtronic designed, manufactured, assembled, promoted and sold to Plaintiff and Class members, were merchantable and fit and safe for ordinary use. Medtronic further impliedly warranted that its Sprint Fidelis leads were fit for the particular purpose of providing prophylactic treatment of patients with a variety of medical issues, including prior myocardial infarction and a limited ejection fraction, spontaneous and/or inducible life-threatening ventricular arrhythmias, and a high risk for developing such arrhythmias.

76. Medtronic further impliedly warranted that its Sprint Fidelis leads were based on

"proven" lead technology and that the Sprint Fidelis leads were easier to implant.

77. Medtronic's Sprint Fidelis leads were defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiff and Class members to severe and permanent injuries and death. Therefore, Medtronic breached the implied warranties of merchantability and fitness for a particular purpose when its leads were sold to Plaintiff and Class members, in that the leads are defective and have fractured and otherwise failed to function as represented and intended.

78. As a direct and proximate result of Medtronic's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff and Class members have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, and economic losses, and are therefore entitled to compensatory damages and equitable relief according to proof.

COUNT III

Negligence

79. Plaintiffs, on behalf of themselves and all others similarly situated, re-allege the allegations contained in the foregoing paragraphs.

80. Medtronic had a duty to Plaintiff and Class members to provide a safe product in design and manufacture, to notify the FDA of design flaws, and to warn the FDA and Class members of the defective nature of the Sprint Fidelis leads. Medtronic breached its duty of reasonable care to Plaintiff and Class members by incorporating a defect into the design of the Sprint Fidelis leads, thereby causing Plaintiff's and Class members' injuries.

81. Medtronic breached its duty of reasonable care to Plaintiff and Class members by manufacturing and assembling the Sprint Fidelis leads in such a manner that they were prone to fracture and fail to operate and malfunction and expose Plaintiff and Class members to life-threatening physical trauma.

82. Medtronic breached its duty of reasonable care to Plaintiff and Class members by failing to notify the FDA at the earliest possible date of known design defects in the leads.

83. Medtronic breached its duty of reasonable care to Plaintiff and Class members by

failing to exercise due care under the circumstances.

84. As a direct and proximate result of the carelessness and negligence of Medtronic as set forth in the preceding paragraphs, Plaintiff and Class members have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages, are entitled to compensatory damages and equitable and declaratory relief according to proof. Medtronic's egregious misconduct alleged above also warrants the imposition of punitive damages against Medtronic.

COUNT IV

Intentional Infliction of Emotional Distress

85. Plaintiffs, on behalf of themselves and all others similarly situated, re-allege the allegations contained in the foregoing paragraphs.

86. Medtronic engaged in extreme and outrageous conduct, knowingly and/or recklessly marketing defective leads, knowingly and/or recklessly concealing a known and potentially fatal defect from Plaintiff and Class members, and knowingly and/or recklessly misrepresenting the quality and usefulness of the Sprint Fidelis leads.

87. As a direct result of Medtronic's misconduct, Plaintiff and Class members have sustained and will continue to sustain physical injuries and/or death, economic losses, and other damages.

88. Medtronic intended to cause Plaintiff and Class members severe emotional distress, or acted with reckless disregard for the Plaintiff's and the Class members' emotional states.

89. Plaintiff and Class members did, in fact, incur (and continue to incur) severe emotional distress as a result of Medtronic's misconduct. Accordingly, Plaintiff and the Class members are entitled to compensatory damages and equitable and declaratory relief according to proof.

90. Medtronic's misconduct alleged above warrants the imposition of punitive damages against Medtronic.

COUNT V

Negligent Infliction of Emotional Distress

91. Plaintiffs, on behalf of themselves and all others similarly situated, re-allege the allegations contained in the foregoing paragraphs.

92. Medtronic carelessly and negligently manufactured, marketed and sold defective Sprint Fidelis leads to Plaintiff and Class members, carelessly and negligently concealed these defects from Plaintiff and Class members, and carelessly and negligently misrepresented the quality, safety and usefulness of the leads.

93. Plaintiff and Class members were directly involved in and directly impacted by Medtronic's carelessness and negligence, in that Plaintiff and Class members have sustained and will continue to sustain severe physical injuries and/or death, economic losses, and other damages as a direct result of the decision to purchase, use and have implanted in their bodies a defective and dangerous product manufactured, sold and distributed by Medtronic.

94. Medtronic's misconduct as alleged above has caused Plaintiff and Class members to suffer severe emotional trauma, physical consequences and long continued emotional disturbance. Plaintiff and Class members are therefore entitled to compensatory damages and equitable and declaratory relief according to proof.

COUNT VI

Violation of Consumer Protection Statutes

95. Plaintiffs, on behalf of themselves and all others similarly situated, re-allege the allegations contained in the foregoing paragraphs.

96. Defendants have a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the defective leads.

97. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the defective leads, and would not have incurred related medical costs.

98. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and

deceptive acts and practices in violation of the state consumer protection statutes listed below.

99. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the defective leads that he would not have paid had Defendants not engaged in unfair and deceptive conduct.

100. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes, as listed below:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §1770, et seq. and Cal. Bus. & Prof. Code § 17200, et seq.;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, et seq.;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, et seq.;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, et seq.;

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, et seq.;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, et seq.;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110a, et seq.;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 6 Del. Code §§ 2511, et seq. and 2531, et seq.;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, et seq.;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, et seq.;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §§10-1-372, et seq., 10-1-392 and 10-1-420;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480-1, et seq.;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, et seq.;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, et seq.;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5-1, et seq.;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.16, et seq.;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Kan. Stat. § 50-623, et seq.;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.170, et seq.;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, et seq.;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 205A, et seq.;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, et seq.;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, et seq.;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann. § 445.901, et seq.;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §§ 325D.43, et seq., 325F.67, et seq. and 325F.68 et seq.;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, et seq.;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Ann. Missouri Stat. § 407.010, et seq.;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Ann. § 30-14-101, et seq.;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, et seq.;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. § 598.0903, et seq.;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, et seq.;

(ee) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, et seq.;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, et seq.;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§ 349 et seq. and 350-e, et seq.;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, et seq.;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. CODE §§ 51-12-01, et seq., and 51-15-01, et seq.;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. § 1345.01, et seq.;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, et seq.;

(ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, et seq.;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, et seq.;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, et seq.;

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, et seq.;

(pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws § 37-24-1, et seq.;

(qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, et seq.;

(rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, et seq.;

(ss) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, et seq.;

(tt) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, et seq.;

(uu) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, et seq.;

(vv) Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, et seq.;

(ww) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, et seq.;

(xx) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. §100.20, et seq.; and

(yy) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-101, et seq.

101. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and

consumers was to create demand for and sell the defective leads. Each aspect of Defendants' conduct combined to artificially create sales of the defective leads.

102. The medical community relied upon Defendants' misrepresentations and omissions in determining which cardiac device to utilize.

103. By reason of the unlawful acts engaged in by Defendants, Plaintiff has suffered ascertainable loss and damages.

104. Defendants violated the applicable consumer fraud statutes designed to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the leads were fit to be used for the purpose for which they were intended, when in fact the leads were defective and dangerous, and by other acts alleged herein. The representations were made in uniform promotional materials.

105. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the applicable consumer fraud statutes. Defendants had actual knowledge of the defective and dangerous condition of the Sprint Fidelis leads, and failed to take any action to cure such defective and dangerous conditions.

106. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff was damaged by paying in whole or in part for these defective leads.

107. As a direct and proximate result of Defendants' violations of state consumer protection statutes, Plaintiff has sustained economic losses and other damages for which he is entitled to statutory, compensatory damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and severally for all general, special and injunctive relief to which Plaintiff is entitled by law. Under statutes enacted in California and all other states, and the District of Columbia, to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Plaintiff and Class members are consumers who purchased Medtronic's Sprint Fidelis leads pursuant to a consumer transaction for personal use and are therefore subject to protection under such legislation.

COUNT VII

Breach of Express Warranties

108. Plaintiffs, on behalf of themselves and all others similarly situated, re-allege the allegations contained in the foregoing paragraphs.

109. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, the internet, and other communications intended for medical patients, and the general public, that the defective leads were safe, effective, fit and proper for their intended use.

110. In allowing the implantation of the defective leads, Plaintiff relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the defective leads were not safe and were unfit for the uses for which they were intended.

111. Through its sale of the defective leads, Defendants are merchants pursuant to Section 2-314 of the Uniform Commercial Code.

112. Any disclaimers of express warranties are ineffectual as they were not provided to Plaintiff or otherwise made known to Plaintiff. In addition, any such disclaimers are unconscionable.

113. As a direct and proximate result of Defendants' breach of express warranty, Plaintiff has sustained economic losses and other damages for which he is entitled to compensatory damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and damages to Plaintiff in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential damages in unconscionable. Defendants are liable to Plaintiff jointly and severally for all damages to which Plaintiff is entitled by law.

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COUNT VIII

Violation of the Minnesota Prevention of Consumer Fraud Act

114. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims For Relief sections of Plaintiffs' Complaint as if fully set forth herein.

115. Defendants intentionally concealed their design and manufacturing defects and failed to disclose the defects for the purpose of continuing to sell and distribute the defective leads.

116. As alleged above, Defendants represented that the defective leads were safe and effective and intended that Plaintiff and his physicians rely on those representations when deciding if Defendants' defective leads were optimal for meeting the Plaintiff's needs.

117. Through these misleading and deceptive statements and false promises, Defendants violated Minn. Stat. § 325F.69.

118. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which he is entitled to statutory, compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and severally for all general, special and equitable relief to which Plaintiff is entitled by law.

COUNT IX

Unjust Enrichment

119. Plaintiffs, on behalf of themselves and all others similarly situated, re-allege the allegations contained in the foregoing paragraphs.

120. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchase of Defendants' defective leads by Plaintiff.

121. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Plaintiff, with full knowledge and awareness that, as a result of Defendants' wrongdoing, Plaintiff was not receiving a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as a reasonable consumer, expected.

122. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the Plaintiff, who is entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT X

Loss of Consortium

123. Plaintiffs hereby incorporate by reference all paragraphs preceding the Claims for Relief section of Plaintiffs' Complaint as if fully set forth herein.

124. At all times relevant hereto, Plaintiff Pamela West, on behalf of herself and all other similarly situated Spouse plaintiffs, has suffered injuries and losses as a result of Plaintiffs' injuries.

125. For the reasons set forth herein, Spouse Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment and for medications and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

126. For the reasons set forth herein, Spouse Plaintiffs have suffered and will continue to suffer the loss of their loved one's support, companionship, services, society, love and affection.

127. For all Spouse Plaintiffs, Plaintiff alleges her marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

128. Spouse Plaintiffs have suffered great emotional pain and mental anguish.

129. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs have sustained and will continue to sustain severe physical injuries severe emotional distress, economic losses, and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Spouse Plaintiffs for all general, special and equitable relief to which Spouse Plaintiffs are entitled by law.

COUNT XI

Declaratory Relief and Medical Monitoring

130. Plaintiffs, on behalf of themselves and all others similarly situated, re-alleges the allegations contained in the foregoing paragraphs.

131. Plaintiff and Class members have no adequate remedy at law and damages cannot adequately compensate Plaintiff and Class members for the injuries suffered and threatened, rendering declaratory, injunctive, and other equitable relief appropriate.

132. Through the unlawful conduct set forth in the preceding paragraphs, Plaintiff and tens of thousands of Class members have been implanted with a device which tends to fracture, and otherwise malfunction. These defects have potentially fatal consequences for many patients who rely upon the presence of the leads connected to the ICDs to regulate their cardiac rhythms.

133. There are medical risks to Plaintiff and Class members associated with having the defective Sprint Fidelis leads explanted, as they have been implanted directly onto the heart wall. Explanation procedures expose Plaintiff and Class members to significant risks attendant to surgery, not least of which are potentially life-threatening infections and other harm.

134. At the same time, Plaintiff and Class members, along with their physicians, must weigh these risks against the possibility that Medtronic's Sprint Fidelis leads will fail or have failed to function as designed, represented and intended, resulting in an increased risk of heart damage, failure and/or death.

135. Accordingly, Plaintiffs, on behalf of themselves and all others similarly situated, requests the following classwide equitable relief:

(a) That Medtronic be ordered to notify all potential Class members of the defective nature of the Sprint Fidelis leads;

(b) That Medtronic be ordered to create a treatment fund, under the continuing jurisdiction and supervision of this Court, to monitor the health of Plaintiff and Class members, and to pay or reimburse Plaintiff and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses caused by Medtronic's wrongdoing; and

(c) Declaratory judgment that Medtronic is liable to Plaintiff and all Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for judgment against Medtronic as follows:

1. For an Order certifying the Class and any appropriate subclasses thereof under the appropriate provisions of Federal Rule of Civil Procedure 23, and appointing Plaintiffs and their counsel to represent the Class;

2. For the equitable relief requested;

3. For compensatory damages according to proof;

4. For punitive or exemplary damages against Medtronic, consistent with the degree of Medtronic's reprehensibility and the resulting harm or potential harm to Plaintiff and the Class, and in an amount sufficient to punish Medtronic and deter others from similar wrongdoing;

5. For all applicable statutory damages under the consumer protection legislation of California, Minnesota, Florida, and all states and the District of Columbia;

6. For declaratory judgment that Medtronic is liable to Plaintiff and Class members for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental expenses, costs and losses caused by Medtronic's wrongdoing;

7. For notice to be disseminated to all Class members who have been implanted with Sprint Fidelis leads;

8. For a restitution and disgorgement of profits;

9. For an award of attorneys' fees and costs;

10. For prejudgment interest and the costs of suit; and

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11. For such other and further relief as this Court may deem just and proper.

DATED: November 8, 2007

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Attorneys for Plaintiffs West and the Class

JURY DEMAND

Plaintiffs, on behalf of themselves and all others similarly situated, hereby demand a trial by jury in this case as to such issues so triable.

DATED: November 8, 2007

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Exhibit B

Medtronic, Inc.
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Urgent Medical Device Information

Sprint Fidelis® Lead Patient Management Recommendations

October 15, 2007

Dear Doctor,

This letter provides important information on Sprint Fidelis lead performance and recommendations for ongoing patient management. Our records indicate that you have implanted or are following patients with Sprint Fidelis leads (Models 6930, 6931, 6948, 6949). In consultation with our Independent Physician Quality Panel, we are voluntarily suspending distribution of Sprint Fidelis leads worldwide. This decision is based on a variety of factors detailed in this letter that when viewed together, indicate that suspension of implantation is the appropriate action. You should no longer implant Sprint Fidelis leads, and you should return any unused product to Medtronic.

Background

As we reported in March 2007, there are two primary locations[1] where chronic conductor fractures have occurred on Sprint Fidelis leads: 1) the distal portion of the lead, affecting the anode (ring electrode) and 2) near the anchoring sleeve tie-down, predominantly affecting the cathode (helix tip electrode), and occasionally the high voltage conductor. High voltage conductor fractures could result in the inability to deliver defibrillation therapy. Anode or cathode conductor fractures (at either location) may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output. The potential for defibrillation lead fracture to result in or contribute to inappropriate therapies or death has been previously reported.[2] As of October 4, 2007, there have been approximately 268,000 Sprint Fidelis leads implanted worldwide. Based on current information, we have identified five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. We have confirmed 665 chronic fractures in returned leads. Approximately 90% of these fractures have occurred in the anode or cathode conductors, while 10% have occurred in the high voltage conductors.

Performance Update

Since our March 21st communication, we have examined six months additional Returned Product Analysis (RPA) and Medtronic System Longevity Study (SLS) data. In addition, we have performed extensive analysis using the Medtronic CareLink® Network (25,000 devices) [see Appendix A]. These data give us confidence in our current understanding of Sprint Fidelis' performance.

RPA of Sprint Fidelis leads shows a survival of 99.2% at 30 months. However, RPA overstates actual performance since it does not account for leads that are not returned. The Medtronic SLS data for the Model 6949 Sprint Fidelis lead indicate 97.7% [+1.3/-3.0] all-cause lead survival at 30 months. This is consistent with our analysis of Medtronic CareLink Network data from approximately 25,000 Sprint Fidelis leads, which indicate 97.7% [+0.6/-0.8] survival at 30 months. These survival rates are not statistically different from the all-cause lead survival of 99.1% [+0.4/-0.8] for the Model 6947 Sprint Quattro® lead at 30 months from the SLS (see Appendix B). However, we expect this difference will become statistically significant over time if the current failure rates remain constant.

Recommendations

Medtronic recommends you consider the following as part of routine follow-up for each patient (see Appendix C)

- To reduce the risk of inappropriate detection and therapy due to oversensing, program VF detection for initial Number of Intervals to Detect (NID) to nominal settings (18/24) or longer at physician discretion and Redetect NID to nominal settings (12/16).
- Turn ON Patient Alert™ for RV Pacing, RV Defibrillation, and SVC Defibrillation impedance. For Concerto® and Virtuoso® devices enrolled on the Medtronic CareLink™ Network, turn ON the CareLink CareAlert® notifications for these same parameters

- To optimize effectiveness of the lead impedance alert:
  - Review V Pacing Lead Performance Trend to determine typical chronic impedance value for the patient (typical values for Fidelis leads should be 350-1,000 ohms).
  - Program lead impedance alert threshold for RV Pacing to 1,000 ohms, if the typical chronic impedance for the patient is ≤ 700 ohms, or
  - Program lead impedance alert threshold for RV Pacing to 1,500 ohms, if the typical chronic impedance for the patient is > 700 ohms.
  - Program lead impedance alert threshold for RV Defibrillation and SVC Defibrillation to 100 ohms.

The patient management recommendations set forth above should increase the likelihood that a fracture will be detected by Patient Alert and/or Medtronic CareAlert notifications and decrease the likelihood of inappropriate therapies. Based on our review of the available data, there does not appear to be a benefit to more frequent follow-up.

Medtronic's Independent Physician Quality Panel believes it is inappropriate to prophylactically remove Sprint Fidelis leads except in unusual individual patient circumstances. We support this position.

Lead extraction carries risks that should be considered in patient management. Published literature suggests major complications (death or surgical intervention) from lead extraction range from 1.4-7.3%.[3,4] As always, with confirmed lead failure the risk of extraction should be weighed against the risk of adding an additional lead (see Appendix D).

Additional Communication

The HRS-recommended Physician Device Advisory Notice for this communication is attached. The information in this letter will be posted on Medtronic.com on October 15th. Consistent with the HRS[5] recommendations on device advisory communications we will be informing patients with affected devices, advising them to contact you for more information. The patient letter will be sent on October 22nd.

We are notifying regulatory agencies of this communication. We will continue to provide performance updates every six months via our Product Performance Report.

Nothing is more important to Medtronic than patient safety. We are committed to answering your questions and keeping you informed. We regret any difficulties this may cause you and your patients. If you have questions or concerns, please contact your Medtronic Representative or Medtronic Technical Services at 1(800) 723-4636 (US).

Sincerely,

Reggie Groves
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Disease Management

Appendix Document Attached

1 The two primary locations described above account for 90% of the chronic fractures identified by RPA. The remaining 10% of chronic fractures occurred in DF-1 connector leg and the proximal portion of the RV coil.
2 Kleemann T, Becker T, Doenges K, et al., K. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. *Circulation*. May 15, 2007; 115(19): 2461 - 2463.
3 Byrd CL, Wilkoff BL, et al. Intravascular extraction of problematic or infected permanent pacemaker leads: 1994-1996. U.S. Extraction Database, MED Institute. *PACE* May 2000; 23(5): 927-928.
4 Bracke FA, Meijer A, vanGelder LM. Lead extraction for device related infections: a single centre experience. *Europace*, May 2004; 6(3): 243-247.
5 Recommendations from the HRS task force on device performance policies and guidelines. Carlson MD, et al. Heart Rhythm Journal 2006, 3, 1250-73.

Exhibit C

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

ATTORNEYS AT LAW

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Northern District of California
450 Golden Gate Avenue, 16th Floor
San Francisco, CA 94102

Re: *In re Rashid Hunter v. Medtronic Inc.*, Case No. 07-cv-6474; *In re Jeneane Baque v. Medtronic, Inc.*, Case No. 07-cv-5352; *In re Willie West, Pamela West v. Medtronic, Inc.*, Case No. 07-cv-5697

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation. This motion has also been filed by ECF in the *Hunter* action.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

742891.1

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
ATTORNEYS AT LAW
EMBARCADERO CENTER WEST
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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the District of Puerto Rico
Clemente Ruiz-Nazario U.S. Courthouse and Federico Degetau Federal Building
150 Carlos Chardon Street
Hato Rey, PR 00918

Re: *In re Russell Nelson et al v. Medtronic, Inc.*, Case No. 07-cv-1969-JAG; *In re David Wood v. Medtronic, Inc.*, Case No. 07-cv-1971-JAG; *In re Frederick Santitoro, Richard Kinney v. Medtronic, Inc.*, Case No. 07-cv-1972-JAG; *In re Norman Black v. Medtronic, Inc.*, Case No. 07-cv-2014; *In re Gilberto Colon-Perez, et al, v. Medtronic, Inc.*, Case No. 07-cv-2021; *In re William E. Storms v. Medtronic, Inc.*, Case No. 07-cv-2049; *In re Gerald Phaup, Jr. v. Medtronic, Inc.*, Case No. 07-cv-2050; *In re Carlos Milan, et al, v. Medtronic, Inc.*, Case No. 07-cv-2064; *In re Diego Maldonado Ocasio, et al, v. Medtronic, Inc.*, Case No. 3:07-cv-2135; *In re Cruz Reyes Rivera, et al, v. Medtronic, Inc.*, Case No. 3:07-cv-2128; *In re Juan Orta-Rodtriguez v. Medtronic, Inc.*, Case No. 3:07-cv-2169

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation. Ms. Fleishman is also counsel for Plaintiffs in the *Nelson, Santitoro* and *Kinney* actions, and this motion has been filed by ECF in those cases.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure
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LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Southern District of Florida
301 North Miami Avenue
Miami, FL 33128

Re: *In re Eugene Clasby v. Medtronic, Inc.*, Case No. 07-cv-22768; *In re Leroy Coffee v. Medtronic, Inc.*, Case No. 07-cv-81094; *In re Herbert Mayo v. Medtronic, Inc.*, Case No. 1:07-cv-23045; *In re John North v. Medtronic, Inc.*, Case No. 07-cv-22764; *In re Doug Venning v. Medtronic, Inc.*, Case No. 07-cv-81056; *In re Mary M. Wardwell as Personal Rep. of the Estate of David P. Wardwell v. Medtronic, Inc.*, Case No. 07-cv-81034

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation. Ms. Fleishman is also counsel for Plaintiffs in the *North* action, and this motion has been filed by ECF in that case.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Southern District of Indiana
Birch Bayh Federal Building and U.S. Courthouse
46 East Ohio Street, Room 105
Indianapolis, IN 46204

Re: *In re Charles R. Phillips v. Medtronic, Inc.*, Case No. 1:07-cv-1556

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

742891.1

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the District of Kansas
500 State Avenue
259 U.S. Courthouse
Kansas City, KS 66101

Re: *In re Phillip S. Brown v. Medtronic, Inc.*, Case No. 07-cv-2542

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

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LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Western District of Louisiana
U.S. Courthouse, Suite 2100
800 Lafayette Street
Lafayette, LA 70501

Re: *In re Mattie Ley Johnson Londo v. Medtronic, Inc.*, Case No. 07-cv-1809; *In re Dianna Sonnier v. Medtronic, Inc.*, Case No. 07-cv-1889

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.,* U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Western District of Louisiana (Monroe Office)
Federal Building, Suite 215
201 Jackson Street
Monroe, LA 71201

Re: *In re Randall Stone v. Medtronic, Inc.*, Case No. 07-cv-1902

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Eastern District of Louisiana
500 Poydras Street, Room C556
New Orleans, LA 70130

Re: *In re Keith Paul Trosclair v. Medtronic, Inc.*, Case No. 07-cv-7565; *In re Henry J. Therior, Earline B. Theriot v. Medtronic, Inc.*, Case No. 07-cv-8441

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the District of Minnesota
746 Federal Building
316 N. Robert Street
St. Paul, MN 55101

Re: *In re Kelly Luisi, Len Stavish v. Medtronic, Inc.*, Case No. 07-cv-4250; *In re Harvey Lee Conway, Jr., et al, v. Medtronic, Inc.*, Case No. 07-cv-4270; *In re Linda J. White v. Medtronic, Inc.*, Case No. 07-cv-4412; *In re Rodney C. Kesti v. Medtronic, Inc.*, Case No. 07-cv-4442; *In re Jesse Noonan v. Medtronic, Inc.*, Case No. 07-cv-4528; *In re Leonard Shapiro v. Medtronic, Inc.*, Case No. 07-cv-4669, *In re Donald Alexander v. Medtronic, Inc.*, Case No. 07-cv-4519

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.,* U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation. Ms. Fleishman is also counsel for Plaintiff in the *Luisi* action, and this motion has been filed by ECF in that case.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

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LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

ATTORNEYS AT LAW

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Western District of Missouri
Charles Evans Whittaker Courthouse
400 East Ninth Street
Kansas City, MO 64106

Re: *In re Kenneth Carlile v. Medtronic, Inc.*, Case No. 07-cv-6110, *In re Ruby McNabb v. Medtronic, Inc.*, Case No. 4:07-cv-0494

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

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LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the District of North Dakota, Southwestern Division
220 East Rosser Avenue
PO Box 670
Bismarck, ND 58502-0670

Re: *In re Winnifred Leverson v. Medtronic, Inc.*, Case No. 1:07-cv-0090

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.,* U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

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LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

ATTORNEYS AT LAW

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www.lchb.com

NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Southern District of West Virginia
PO Box 2546
Charleston, WV 25329

Re: *In re Ted Carter v. Medtronic, Inc.*, Case No. 2:07-cv-0752

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

742891.1

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

ATTORNEYS AT LAW

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mail@lchb.com
www.lchb.com

NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Northern District of Iowa
101 First Street SE
Cedar Rapids, IA 52401

Re: *In re Violet Klein, Brad Klein v. Medtronic, Inc.*, Case No. 1:07-cv-0104

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

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LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

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NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Middle District of Louisiana
777 Florida Street, Ste. 139
Baton Rouge, LA 70801

Re: *In re Vertrena Wilkinson Crum v. Medtronic, Inc.*, Case No. 3:07-cv-0923

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

742891.1

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

ATTORNEYS AT LAW

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mail@lchb.com
www.lchb.com

NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the District of New Jersey
Clarkson S. Fisher Building and US Courthouse
402 E. State Street, Room 2020
Trenton, NJ 08608

Re: *In re E. David Barrick v. Medtronic World Headquarters*, Case No. 3:07-cv-4393

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

742891.1

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

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www.lchb.com

NEW YORK
NASHVILLE

January 2, 2008

VIA US MAIL

Clerk of Court
United States District Court for the Western District of Texas
655 East Durango Blvd., Rm. G65
San Antonio, TX 78206

Re: *In re Salina Marie Badillo v. Medtronic, Inc.*, Case No. 5:07-cv-0942

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on January 2, 2008 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

742891.1

LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP

ATTORNEYS AT LAW

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FACSIMILE: (415) 956-1008
mail@lchb.com
www.lchb.com

NEW YORK
NASHVILLE

December 31, 2007

VIA US MAIL

Clerk of Court
United States District Court for the Western District of Texas
655 East Durango Blvd., Rm. G65
San Antonio, TX 78206

Re: *In re Salina Marie Badillo v. Medtronic, Inc.*, Case No. 5:07-cv-0942

Dear Sir or Madam:

On behalf of Wendy R. Fleishman, counsel for Plaintiff in the related action *Rashid Hunter v. Medtronic Inc.*, U.S.D.C. ND Cal. 07-cv-6474, please find enclosed for your records the Motion of Plaintiff Rashid Hunter for Joinder in the Motion of Frederick Santitoro and Richard Kinney for Transfer and Consolidation of Related Action Pursuant to 28 U.S.C. §1407. This motion was sent out for filing on December 31, 2007 in the Judicial Panel of Multidistrict Litigation.

Very truly yours,

Adelina Acuña
Paralegal

Enclosure

742891.1

Exhibit D

Medtronic

Medtronic, Inc.
Cardiac Rhythm Disease Management
7000 Central Avenue NE
Minneapolis, MN 55432-3576
www.medtronic.com

763514.4000

March 21, 2007
Re: Physician Information - Sprint Fidelis lead

Dear Doctor,

Medtronic has received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers with Sprint Fidelis leads. While current overall Sprint Fidelis performance is consistent with other leads, Medtronic is actively investigating these reports, has reviewed them with our Independent Physician Quality Panel, and would like to share what we know at this time.

Through detailed assessment of reported fractures, we have identified two primary locations where conductor fractures have occurred: 1) distal portion of the lead and 2) near the anchoring sleeve tie down. The distal conductor fractures affect the anode (ring electrode) and fractures that occur around the anchoring sleeve affect the cathode (helix tip electrode). Fractures at both locations appear to present clinically as over-sensing, increased interval counts and inappropriate shocks. Medtronic has worked closely with physicians who have experienced fractures and conducted significant bench testing in an attempt to reproduce the fractures and identify root cause. At this point, our investigation suggests that variables within the implant procedure may contribute significantly to these fractures.

For distal conductor fractures, our investigation has identified severe bending or kinking of the distal end of the lead over the lead body while passing through tortuous vasculature as a significant contributing factor. If the lead is severely bent or kinked at the distal end, the conductor may be compromised such that the conductor may fracture after implant due to chronic fatigue from natural cardiac motion. The venous structure or pathway, venous access location, length of introducer sheath and lead insertion force are all factors that may contribute to severe bending or kinking of the lead. Medtronic recommends avoiding severe bending or kinking of the lead during implantation. If you encounter excessive resistance resulting in severe bending or kinking while advancing the lead, please remove the lead and return it to Medtronic.

For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area. We are still investigating and actively partnering with physicians to better understand this type of fracture. If excessive kinking or bending is observed during lead suturing and/or pocket formation, Medtronic recommends the lead be re-sutured and/or the pocket reassembled per guidelines in the Medtronic lead implant manual. In addition, positioning the anchoring sleeve against or near the vein may be helpful.

Sprint Fidelis lead models 6949, 6948, 6931, and 6930 were market released in the U.S. and internationally in September and October 2004. Performance of model 6949, the Sprint Fidelis lead currently followed in our System Longevity Study, indicates survival is 98.9% at two years. Sprint Fidelis 6949 performance based on return product analysis shows 99.86% chronic fracture-free survival at two years. Both evaluation methods suggest performance is in line with other Medtronic leads (see relative Medtronic performance data on the following page) and consistent with lead performance publicly reported by other manufacturers.

Medtronic is committed to ensuring the highest standards of product reliability. As we learn more, we will share additional information and technical guidance through our sales and technical representatives. If you have questions or concerns, please contact your Medtronic Representative or Medtronic Technical Services at 1-800-723-4636 (US).

Sincerely,

Reggie Groves
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Disease Management
Medtronic, Inc.

Alleviating Pain · Restoring Health · Extending Life

Relative Performance of Sprint Fidelis 6949 vs. other Medtronic Leads

Sprint Fidelis is enrolled in Medtronic's System Longevity Study which tracks chronic lead performance. At this time, we have enrolled 497 model 6949 leads in this study with 6,166 cumulative months of follow up. Results indicate survival is 98.9% at two years based on complications occurring beyond 30 days of implant. The following table summarizes data from Medtronic's System Longevity Study comparing the Sprint Fidelis lead with Sprint and Sprint Quattro:

System Longevity Study

Lead Model	Survival at 2 years
Sprint (6945)	99.1%
Sprint Quattro (6947)	99.3%
Sprint Fidelis (6949)*	98.9%

While Medtronic believes the most accurate method to assess lead performance is the System Longevity Study, we recognize the number of Sprint Fidelis leads followed to date in the System Longevity Study is not sufficient to be used as the sole means of gauging overall performance. Therefore, we have also examined the chronic fracture performance of this lead through Returned Product Analysis. The Sprint Fidelis lead appears to perform in line with other Medtronic leads in the market:

Returned Product Analysis

Lead Model	Chronic Fracture-Free Survival at 2 years
Sprint (6945)	99.92%
Sprint Quattro (6947)	99.94%
Sprint Fidelis (6949)*	99.86%

* Due to the small implant sample size of Sprint Fidelis models 6948, 6931, and 6930, the System Longevity Study and Returned Product Analysis data is based on Sprint Fidelis 6949 leads only.

Exhibit E

U.S. DISTRICT COURT - JUDICIAL CASELOAD PROFILE

CALIFORNIA NORTHERN			12-MONTH PERIOD ENDING SEPTEMBER 30							
			2006	2005	2004	2003	2002	2001	Numerical Standing	
									U.S.	Circuit
OVERALL CASELOAD STATISTICS	Filings*		8,683	6,362	6,727	6,919	7,887	6,841		
	Terminations		6,983	6,966	6,471	7,094	6,675	6,069		
	Pending		8,157	6,557	7,267	7,567	7,958	6,928		
	% Change in Total Filings	Over Last Year		36.5					4	1
		Over Earlier Years			29.1	25.5	10.1	26.9	10	2
Number of Judgeships			14	14	14	14	14	14		
Vacant Judgeship Months**			.0	.0	.0	3.1	12.0	3.0		
ACTIONS PER JUDGESHIP	FILINGS	Total	620	455	480	494	563	489	11	3
		Civil	558	390	413	424	510	439	6	2
		Criminal Felony	37	39	44	47	42	50	82	12
		Supervised Release Hearings**	25	26	23	23	11	-	36	12
	Pending Cases		583	468	519	541	568	495	12	2
	Weighted Filings**		621	543	581	631	598	610	5	2
	Terminations		499	498	462	507	477	434	28	5
	Trials Completed		8	10	10	11	11	11	91	14
MEDIAN TIMES (months)	From Filing to Disposition	Criminal Felony	11.2	12.6	11.1	11.7	11.8	10.1	75	11
		Civil**	7.4	9.8	8.2	10.6	9.5	9.1	11	3
	From Filing to Trial** (Civil Only)		25.0	28.0	22.5	30.3	23.5	22.7	41	5
OTHER	Civil Cases Over 3 Years Old**	Number	528	530	430	377	475	335		
		Percentage	7.3	9.5	6.9	5.7	6.7	5.6	60	7
	Average Number of Felony Defendants Filed Per Case		1.5	1.5	1.4	1.5	1.4	1.5		
	Jurors	Avg. Present for Jury Selection	59.09	55.21	61.19	65.00	66.42	60.46		
		Percent Not Selected or Challenged	43.2	31.0	48.9	40.9	47.2	42.2		

2006 CIVIL AND CRIMINAL FELONY FILINGS BY NATURE OF SUIT AND OFFENSE

Type of	TOTAL	A	B	C	D	E	F	G	H	I	J	K	L
Civil	7812	128	2118	1540	105	23	487	577	481	464	745	105	1039
Criminal*	507	16	58	134	70	89	18	28	8	9	15	27	35

* Filings in the "Overall Caseload Statistics" section include criminal transfers, while filings "By Nature of Offense" do not.
** See "Explanation of Selected Terms."